

## ARTICLES

### **Prescriptions sans Frontières (or How I Stopped Worrying About Viagra on the Web but Grew Concerned About the Future of Healthcare Delivery)**

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#### INTRODUCTION

Internet-based prescribing and dispensing are poised to become major components of healthcare delivery in the United States: In 2003, eighteen percent of online U.S. households purchased prescription drugs online, a number expected to grow to twenty-seven percent in 2004.<sup>1</sup> Together, this infusion of technology and the broader trend toward increased prescribing<sup>2</sup> are changing the landscape of American healthcare, and the manner in which the legal system interacts with these controversial millennial delivery models will shape the future of healthcare.

This Article explores the policy issues and legal or regulatory structures currently applied to prescribing and dispensing. Much of the controversy surrounding Internet prescribing and dispensing can be

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1. Eric G. Brown with Bradford J. Homes et al., *Forrester's Top 10 Healthcare Predictions for 2004* (Dec. 15, 2003), at <http://www.forrester.com/ER/Research/Brief/0,1317,33444,00.html>.

2. See, e.g., Press Release, Health Affairs, Doctors Prescribing More Drugs? (July 9, 2002), [http://www.healthaffairs.org/press/In\\_The\\_News\\_070902.htm](http://www.healthaffairs.org/press/In_The_News_070902.htm).

attributed to the unsavory origins of these initiatives: Many of the early providers have been illegal or marginally legal businesses.<sup>3</sup> This Article argues that the threat posed by rogue prescribing and dispensing does not justify the level, style, and mechanics of current regulation. The Article further argues that current and emerging regulation may chill the development of lawful, efficient, necessary, and patient-friendly services and recommends alternate approaches.

Part I of the Article sets out the key distinguishing features of the aforementioned initiatives and suggests that simple confusion between different and emergent models seem to be misleading legislators and regulators and imperiling patient choice. Part II discusses current regulation of Internet prescribing and dispensing and addresses the areas that most concern regulators. In the process, it examines the regulation of Internet prescribing by state licensing boards and the controversy surrounding transnational prescription dispensing.

Parts III and IV of the Article then look beyond the current forms of Internet prescribing and dispensing to identify the stakeholders and critically analyze the regulatory themes that populate the landscape. These themes, including those labeled as uneasy federalism, under-regulation, and over-regulation, help us better understand the ways our legal and regulatory systems create disincentives to the adoption of new technologies or business models. Part V of the Article describes the steps necessary to maintain rigorous control over healthcare quality while avoiding disincentives to the provision of the next generation of effective and efficient healthcare. More importantly, it suggests positive steps (both legal and structural) necessary to create a prescribing and dispensing environment that is lawful, patient-friendly, and progressive in integrating e-health solutions into standard care practices.

## I. BACKGROUND: ISSUES AND TERMINOLOGY

To better understand the impact of regulation on Internet prescribing and dispensing, it is important to appreciate the broader and highly varied landscape of technologically-mediated healthcare. It is also critical to distinguish between the overlapping and frequently confusing labels applied in the relatively immature e-health domain.

In the early twentieth-century there were recorded attempts at what we now call remote imaging or PACS (Picture Archiving and Communications

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3. See discussion *infra* notes 18-20, 27-29 and accompanying text.

Systems).<sup>4</sup> However, the first successful iterations of telemedicine<sup>5</sup> were primarily audio educational teleconferences in the 1950s.<sup>6</sup> By the 1960s, rudimentary telemedicine networks had added video, leading to the first remote consultations.<sup>7</sup> As POTS (Plain Old Telephone System) gave way to faster ISDN (Integrated Services Digital Networks) and subsequent high-speed networks, increasingly sophisticated data, such as charts and x-rays, were added to the telemedical consultation mix.<sup>8</sup>

Telemedicine began as a narrow construct—a consultation-based model of diagnosis and occasionally treatment.<sup>9</sup> In the traditional telemedicine model a primary (or originating) physician uses technology (be it phone, e-mail, or interactive video) to connect to a consulting (or remote) physician; the primary physician may provide the consulting physician with access to a patient's chart, x-ray, or other medical information.

Technological developments have allowed telemedicine to move beyond its early intrastate models to interstate and international projects.<sup>10</sup>

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4. Travis Wheeler, *In the Beginning . . . Telemedicine and Telepsychiatry*, 2 TELEMEDICINE TODAY 2 (1994).

5. In this Part, I describe telemedicine's original meaning—i.e., the consultative interaction between a patient, an on-site health professional, and a distant physician. *See infra* text accompanying note 9. In recent years, telemedicine has increasingly been used as an umbrella term, encompassing a broad range of technologically-mediated interactions. *See infra* note 10 and text accompanying note 12. I posit that continued use of a narrow definition of telemedicine is preferable for its specificity, and other terms, such as telehealth, are more appropriate as broadly inclusive references. *See infra* text accompanying note 13.

6. Wheeler, *supra* note 4, at 2. Audio educational teleconferences were first used in psychiatry. *See* Tracy D. Gunter et al., *Misinformed Regulation of Electronic Medicine Unfair to Responsible Telepsychiatry*, 31 J. ACAD. PSYCHIATRY L. 10 (2003).

7. Wheeler, *supra* note 4, at 4.

8. *See* TELEMEDICINE: A GUIDE TO ASSESSING TELECOMMUNICATIONS FOR HEALTH CARE 34-38 (Marilyn J. Field ed., 1996) [hereinafter TELEMEDICINE GUIDE].

9. *Id.* at 44-46.

10. Much of the technological innovation in telemedical services, particularly in the use of microwave and satellite technologies, has been driven by the military and NASA. *Id.* at 39. Increasingly, traditional bricks-and-mortar healthcare entities have invested heavily in imaging technologies which enable store-and-forward type applications. *See, e.g., Teleradiology FAQ*, Hospital for Special Surgery, at [http://www.imaginghss.org/patient/dri-pat\\_fa\\_q\\_telerradio.htm](http://www.imaginghss.org/patient/dri-pat_fa_q_telerradio.htm) (last visited Apr. 15, 2004); *The Apollo Telepathology System*, Apollo Telemedicine, at <http://www.apollotelemedicine.com/solutions/telepathology> (last visited Apr. 15, 2004). These applications provide their physicians and consultants with widespread remote access to patient data. *See, e.g.,* Scott A. Edelstein, *Careful Telemedicine Planning Limits*

Once it became possible for the remote physician to observe and communicate directly with the patient, telemedicine practice began to deemphasize the importance and role of the “local” physician; in many instances, nurses, nurse practitioners, and IT technicians may now substitute for the local physician.<sup>11</sup>

More recently, the “telemedicine” label has been applied to fully disintermediated models—that is, where there is no on-site health professional and technology alone links patients to distant healthcare providers. For example,

in telehome medicine (technologically-mediate home care) patients interact with monitoring or diagnostic appliances that transmit results to healthcare professionals.<sup>12</sup> Rather than stretching the scope of “telemedicine” to include the full range of remote diagnosis and treatment, store-and-forward technologies, telehome medicine and other disintermediated models, “telehealth”<sup>13</sup> is a broader term that more easily captures all of this. However, the fact that telehealth is an appropriate term to describe these related technologies should not suggest that they necessarily merit collective regulatory treatment.

Extending well beyond the scope of terms like telemedicine or even telehealth, “e-health” is now the accepted reference for the many varied modes of technologically-mediated healthcare.<sup>14</sup> E-health includes telehealth and also encompasses Internet-based prescribing and dispensing, e-prescribing,<sup>15</sup> health advice websites, online continuing medical education and health care procurement.<sup>16</sup> E-health stretches beyond Internet-based commercial activities (commonly referred to as “e-commerce”) to include technologically-mediated healthcare more generally. It includes the accelerating incorporation of technology into traditional bricks-and-mortar healthcare—from reimbursement and

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*Costly Liability Exposure*, HEALTHCARE FIN. MGMT., Dec. 1999, [http://articles.findarticles.com/p/articles/mi\\_m3257/is\\_12\\_53/ai\\_58185760](http://articles.findarticles.com/p/articles/mi_m3257/is_12_53/ai_58185760).

11. TELEMEDICINE GUIDE, *supra* note 8, at 44-46.

12. *Id.*

13. According to Nebraska law, “Telehealth means the use of telecommunications technology by a healthcare practitioner to deliver healthcare services within his or her scope of practice at a site other than the site where the patient is located . . . .” NEB. REV. STAT. § 71-8503 (2002).

14. See Nicolas P. Terry, *Structural and Legal Implications of e-Health*, 33 J. HEALTH L. 606 n.1 (2000); see also G. Eysenbach, Editorial, *What Is e-Health?*, 3 J. MED. INTERNET RES. e20 (2001), <http://www.jmir.org/2001/2/e20/>.

15. *Infra* note 17 discusses the definition of e-prescribing.

16. See Terry, *supra* note 14.



insurance transactions, to longitudinal electronic medical records, to computerized physician order entry (CPOE) systems, to surgery robots—to improve the quality or efficiency of healthcare. Ironically, e-health is unlikely to remain a meaningful label: The rapid deployment of technologies in the health arena, fuelled by the need to reduce medical and medication adverse events and the urgent imperative to remove administrative costs, will rapidly blur the distinction between traditional healthcare delivery and e-health.

Internet prescribing is a particularly important subset of e-health. It is the practice of providing access to prescription drugs when the primary contact between patient and prescriber is Internet or email-based.<sup>17</sup> Many of the businesses involved in such practices are completely disconnected from any model of responsible medical practice.<sup>18</sup> They frequently dabble in controlled substances or maintain a “side business” to perform credit

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17. Care must be taken to distinguish the term “e-prescribing” (electronic prescribing) from Internet prescribing which may result in electronic prescriptions. In its simplest forms, e-prescribing consists of handheld devices that improve prescription writing or dispensing; they are frequently used by physicians in hospitals. (Admittedly, given e-prescribing’s narrow definition, its use of the prefix “e-” is anomalous; elsewhere the prefix “e-” indicates reliance on internet functionality, as in “e-commerce,” or technological-mediation more generally, as in “e-health.”)

There are direct cost-savings associated with e-prescribing’s use of electronic interfaces, and the use of such interfaces will expand exponentially as the full HIPAA electronic data interchange (EDI) and longitudinal patient records come online. *See* Nicolas P. Terry, *An eHealth Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation*, 27 AM. J. L. & MED. 361, 365-66, 370 (2001). At present, however, the dominant reason for adopting such technologies lies in their potential for reducing medical error. *See generally* CAL. HEALTH CARE FOUND., E-PRESCRIBING (2001), <http://www.chcf.org/documents/hospitals/EPrescribing.pdf>; CAL. HEALTH CARE FOUND., IMPROVING DRUG PRESCRIBING PRACTICES IN THE OUTPATIENT SETTING: A MARKET ANALYSIS (2002), <http://www.chcf.org/documents/ihealth/ImprovingDrugPrescribing.pdf>.

Electronic prescription refers to the movement away from requiring a conventional written prescription provided to a patient by a physician that is then manually transmitted to a pharmacy. State laws increasingly allow for a purely electronic prescription and resultant transmittal. *See, e.g.*, MASS. GEN. LAWS ch. 94C, § 23 (Supp. 2004) (“A prescription may be transmitted electronically with the electronic signature and electronic instructions of the prescriber, and shall be transmitted directly from the prescriber to the pharmacy designated by the patient without alteration of the prescription information, except that third-party intermediaries may act as conduits to route the prescription from the prescriber to the pharmacy.”).

18. *See, e.g.*, Gilbert M. Gaul & Mary Pat Flaherty, *Doctors Medicate Strangers on Web; Some Physicians Face Own Troubles*, WASH. POST, Oct. 21, 2003, at A1.

card fraud or other scams.<sup>19</sup> Others are far greyer and make for the most difficult policy and regulatory choices. These superficially professional sites involve online “diagnosis” prior to prescribing. Subsequently, they generate a prescription that they dispense or, more likely, is dispensed through an Internet-based fulfillment partner.<sup>20</sup> What they have in common is best described as an opportunistic physician-patient “relationship” that is entered into for a single purpose (and often a solitary transaction)—the purchase of a specific drug.

Internet dispensing is a potentially far larger business than Internet prescribing, and much of the existing traffic is facially lawful, premised on a valid U.S. prescription that is far more likely to have been written by a patient’s primary care provider than by a Perl script<sup>21</sup> on a website. In 2001, legal Internet and mail-order dispensing accounted for only \$28 billion of the \$164 billion in drug sales, but it is the fastest growing segment of the pharmacy industry and is predicted to double each year in the near term.<sup>22</sup> These legal Internet-based pharmacies and prescription fulfillment businesses, such as Drugstore.com, (often referred to in the press as “e-pharmacies”) are desperate to differentiate themselves from their less reputable brethren<sup>23</sup> and to recapture the business they are losing to Canadian pharmacies.<sup>24</sup> They possess multiple state pharmacy licenses and, frequently, Verified Internet Pharmacy Practice Sites (VIPPS) accreditation. Formalism aside, these legal Internet-based pharmacies are distinguishable by reference to their business model; they do not offer prescribing services but fill prescriptions that, while frequently electronically transmitted, are written by a traditional healthcare provider.

Overlapping conceptually with these legal Internet-based pharmacies are Pharmacy Benefits Managers (PBMs), prescription fulfillment services that increasingly are part of the managed care bundle. A growing number of health plans and employers seek to control pharmaceutical costs by contracting with a PBM, such as Medco Health or ExpressScripts, to

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19. Mary Pat Flaherty & Gilbert M. Gaul, *Lax System Allows Criminals To Invade the Supply Chain*, WASH. POST, Oct. 22, 2003, at A1.

20. See *infra* text accompanying notes 408-415.

21. For examples of the use of Perl scripts generally, see The CGI Resource Index, at [http://cgi.resourceindex.com/Programs\\_and\\_Scripts/Perl/](http://cgi.resourceindex.com/Programs_and_Scripts/Perl/) (last visited July 29, 2004).

22. See Bob Tedeschi, *As Baby Boomers Grow Older, Online Prescription Drug Sales Are Showing Steady Growth*, N.Y. TIMES, Dec. 16, 2002, at C16.

23. See Gilbert M. Gaul & Mary Pat Flaherty, *Warnings Target Rogue Drug Sites*, WASH. POST, Oct. 24, 2003, at A7.

24. See Bob Tedeschi, *As the Debate Continues, Opinions Are Divided over the Merits of Allowing Online Drug Purchases from Canada*, N.Y. TIMES, Mar. 8, 2004, at C4.

manage the fulfillment side of the patient benefits package.<sup>25</sup> The larger PBMs have their own online pharmacies or have contracted with Internet-based pharmacies for prescription fulfillment, threatening the heretofore dominant role of bricks-and-mortar pharmacies.<sup>26</sup>

In contrast to the legal Internet-based pharmacies, illegal pharmacies generally employ a composite model in which prescribing and dispensing businesses overlap. For example, it is not uncommon to see a portal-style advice site that drives users first to an online diagnosis and then on to Internet dispensing.<sup>27</sup> Some Internet addresses that seem to be cohesive, one-stop diagnosis and prescribing businesses in fact have outsourced to separate fulfillment businesses.<sup>28</sup> Even though the domain names for these businesses may “look” American (i.e., dot.com), it is likely that a large percentage are based offshore.<sup>29</sup>

## II. REGULATING INTERNET PRESCRIBING AND DISPENSING

It is not disputed that Internet prescribing and dispensing require close regulation and that some market participants may merit criminal prosecution. Unfortunately, to date, the regulatory routes chosen tend to be conceptually awkward and operationally flawed; so, too, have been the medical community's efforts to self-regulate. An unfortunate byproduct of

25. In some cases, HMOs have opted to develop their own in-house Internet prescription fulfillment services, instead of contracting with a PBM. For a summary of HMO activity and models, see *Health Plan Strategies for Pharmacy Benefit Management*, MANAGED CARE WK., Jan. 13, 2003, at <http://www.aishealth.com/DrugCosts/HMOstrategies.html>. For the technological structure and other details of Medco, a major PBM, see Alan Cohen, *Online Prescriptions*, PC MAG., Aug. 19, 2003, at 68, <http://www.pcmag.com/article2/0,4149,1204843,00.asp>.

26. See *The Internet's Drug Lords*, INDUSTRY STANDARD, Apr. 10, 2000, <http://www.thestandard.com/article/0,1902,13407,00.html>; Associated Press, *Retail Pharmacies Fight for Share in Medicare Bill* (Oct. 21, 2003), available at <http://www.foxnews.com/story/0,2933,100595,00.html>.

27. Indeed, Internet businesses may register multiple domain names, feeding their single business from multiple or transient storefronts.

28. See, e.g., Anelia K. Dimitrova & Tony Leys, *Government Closes Dubuque Pharmacy over Internet Orders*, DES MOINES REG., Sept. 13, 2003, at 1A (describing how federal and state agents shut down a neighborhood pharmacy suspected of fulfilling orders for a Virgin Islands-based Internet company).

29. For example, Buymeds.com is based in the Virgin Islands but fulfills its orders through U.S. bricks-and-mortar pharmacies. See *Pharmacy Linked to Internet Sales Ordered Closed*, USA TODAY, Sept. 12, 2003, available at [http://www.usatoday.com/tech/news/techpolicy/2003-09-12-pharmacy\\_x.htm?csp=15](http://www.usatoday.com/tech/news/techpolicy/2003-09-12-pharmacy_x.htm?csp=15).

this imperfect regulation may be the chilling of responsible practices.

### *A. Traditional Licensure*

The monopoly granted to physicians to prescribe and pharmacists to dispense vests the regulation of pharmaceutical distribution in the hands of state licensure systems.<sup>30</sup> The modern legal history of medical practice acts, licensure, and discipline began in the 1870s with the enactment of state statutes governing the licensing of physicians<sup>31</sup> and pharmacies.<sup>32</sup> The role of the state was sanctioned in 1889, when the Supreme Court denied a due process challenge to a West Virginia medical practice act which required state licensure of physicians.<sup>33</sup> From this point onward, the state police power has been widely recognized as the source of licensure regulation—since then only states have licensed physicians.<sup>34</sup> Pharmacy licensure also remains resolutely state-based, although the reciprocity process and standardized examinations administered by the National Association of Boards of Pharmacies (NABP) have pushed the profession closer to national standards.<sup>35</sup>

Physician mobility in the early part of the twentieth century led to

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30. See, e.g., AZ. STAT. § 32-1961(A) (2000).

31. Medical licensure statutes enforced by state medical boards have existed for over two hundred years, and historical antecedents aimed at quackery and overcharging date back almost four hundred years. However, after the Civil War, licensure went into decline in the hands of local medical societies and inferior medical schools. Thus, the modern history of practice acts and licensure statutes did not truly begin until Texas enacted such legislation in 1873. ROBERT C. DERBYSHIRE, *MEDICAL LICENSURE AND DISCIPLINE IN THE UNITED STATES* 3-12 (1969); see Texas State Bd. of Med. Examiners, *Board of Medical Examiners' History*, at <http://www.tsbme.state.tx.us/boards/mbhis.htm> (last visited Apr. 12, 2004).

32. CARL T. MARCOS, *PHARMACY AND THE LAW* 42 (1984). Licensure statutes began to appear in the 1870s; they continue to focus on drug preparation and premises. *Id.*

33. *Dent v. Virginia*, 129 U.S. 114 (1889) (upholding 1882 W. Va. Act 93, §§ 9, 15). The Court explained:

The power of the State to provide for the general welfare of its people authorizes it to prescribe all such regulations as, in its judgment, will secure or tend to secure them against the consequences of ignorance and incapacity as well as of deception and fraud. . . . The nature and extent of the qualifications required must depend primarily upon the judgment of the State as to their necessity.

*Id.* at 122.

34. See Kevin Outterson, *Health Care, Technology and Federalism*, 103 W. VA. L. REV. 503, 505-09 (2001).

35. MARCOS, *supra* note 32, at 27.

discussions of reciprocity and national (or uniform) licensure—issues that the Federation of State Medical Boards has nurtured, albeit inconclusively, since its founding in 1912.<sup>36</sup> Today, a modern rationale for *state* as opposed to *national* licensure seems difficult to identify. The supposed premise for state licensure is the desirability of regulatory heterogeneity based on geographically distinct economic, religious, or other social policies. Malpractice law,<sup>37</sup> national health quality regulators, accreditation systems, and even state boards themselves<sup>38</sup> have recognized that medical practice, as well as its training, testing, and literature, is national in scope.<sup>39</sup> Healthcare workers and consumers are highly mobile and large integrated healthcare providers have more in common with national or multinational corporations than the local hospitals of an earlier age. Protection of the public is a laudable goal, but not one that requires the Balkanization of the medical profession.<sup>40</sup> Contemporary state licensure justifies local professional fiefdoms, perpetuates parochialism, and encourages anti-competitive protectionism.<sup>41</sup>

The current state medical board systems and analogous pharmacy systems have two key functions: gate-keeping via licensure and quality

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36. DERBYSHIRE, *supra* note 31, at 8-9. Some progress was made, however, with the establishment of the Federation Credentials Verification Service in 1996. See Federation Credentials Verification Service, at [http://www.fsmb.org/fcvs\\_program/cvrhome.htm](http://www.fsmb.org/fcvs_program/cvrhome.htm). See also FED'N OF STATE MED. BDS., REPORT OF THE SPECIAL COMMITTEE ON LICENSE PORTABILITY (2002), <http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/license%20portability.htm> (last visited Apr. 19, 2004); *infra* text accompanying note 464.

37. See, e.g., *Sheeley v. Memorial Hosp.*, 710 A.2d 161 (R.I. 1998); *Hall v. Hilbun*, 466 So. 2d 856 (Miss. 1985); *Morrison v. MacNamara*, 407 A.2d 555 (D.C. 1979).

38. See, e.g., *Gabri v. Rhode Island Bd. of Med. Licensure & Discipline*, No. 97-4344, 1998 R.I. Super. LEXIS 36 (approving use of expert testimony to determine a national standard in sexual misconduct hearing).

39. On the role of the federal government in healthcare delivery, see Outterson, *supra* note 34, at 515-20.

40. There is even less contemporary rational for making the licensure of physicians state-based than there is for having state bar requirements for lawyers. State laws, customary practices, and client expectations do in fact vary across state lines. The same cannot be said for human physiology. See, e.g., *Supreme Court of Virginia v. Friedman*, 487 U.S. 59, 68 (1988) (holding that state bar residency requirement violated privileges and immunities clause, but apparently approving of state requirements designed to demonstrate familiarity with state law).

41. See DERBYSHIRE, *supra* note 31, at 13-31; STANLEY J. GROSS, OF FOXES AND HEN HOUSES: LICENSING AND THE HEALTH PROFESSIONS 9 (1984).

control via standard-setting and discipline.<sup>42</sup> Arguably, medical licensure alone reveals more about qualifications than quality. The pace of quality assurance is instead set by federal and accreditation-based reporting and institutional peer review, as well as managed care contracting, which identifies pools of approved providers for patients.<sup>43</sup> Although, for example, state medical boards have followed state malpractice law by adopting national standards for quality and ethics,<sup>44</sup> the requirement of licensure and the concept of disciplinary jurisdiction continue to be interpreted, implicitly or explicitly, as fundamentally intrastate concepts.<sup>45</sup> Thus, the presence of the physician and patient in separate states (interstate practice)—as is frequently the case with technologically-mediated care—implicates discrete and frequently asymmetrical regulatory systems.<sup>46</sup>

State medical boards are not only hostile to interstate practice, but also tend to be skeptical of non-traditional forms of practice,<sup>47</sup> putting even intrastate practice that is technologically-mediated at disciplinary risk. Such disciplinary scrutiny likely has its roots in customary standards, professional conservatism, or even softly articulated protectionism. Nonetheless, state licensure statutes have been able to accommodate two modest technology-induced changes in the practice of medicine. First, when patients travel out of state and then realize they have left their medications behind, they may phone or email their physician for a replacement prescription.<sup>48</sup>

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42. See, e.g., *Sugarman v. Bd. of Registration in Med.*, 662 N.E.2d 1020, 1023 (Mass. 1996) (noting the broad authority of medical boards “to sanction physicians for conduct which undermines public confidence in the integrity of the medical profession”).

43. See GROSS, *supra* note 41, at 16-21. See generally Nicolas P. Terry, *When the “Machine That Goes ‘Ping’” Causes Harm: Default Torts Rules and Technologically-Mediated Health Care Injuries*, 46 ST. LOUIS U. L.J. 37 (2002).

44. See *supra* note 37 and accompanying text.

45. The conceptual and operational basis of state licensure and disciplinary jurisdiction is the idea of the “practice of medicine”—a term of art referring to legally permitted provisions of allopathic medicine. Implicitly or explicitly, that foundational concept is interpreted to mean the practice of medicine *in a given state*. See, e.g., KY. REV. STAT. ANN. §311.560(1) (Michie 2001); CAL. BUS. & PROF. CODE § 2052(a) (West 2003).

46. This dynamic becomes even more complicated once the location of web or mail servers in additional states is considered. See, e.g., *United States v. Kammersell*, 7 F. Supp. 2d 1196 (C.D. Utah 1998), *aff’d* 196 F.3d 1137 (10th Cir. 1999) (allowing indictment for interstate transmission of a threat between intrastate actors because of the routing of threatening email through server in remote state).

47. See *infra* notes 434-442 and accompanying text.

48. See, e.g., ALA. CODE § 34-24-505(a) (1975) (emergencies); *id.* § 34-24-505(b)

Second, inherent to all professions is the practice of consultation—the formal or informal (that is, remunerated or unremunerated) discussion of a case between professionals. It is now accepted that this will occur among physicians across technological media.<sup>49</sup>

### *B. Telemedicine Regulation*

Traditional telemedicine—the use of communication technology to facilitate long-distance consultation—was readily accepted under state regulatory systems. There are several possible explanations for the absence of controversy. First, it may be that most telemedicine consults have historically been *intrastate* in nature. Second, cost factors have constrained the number of such consults because of the limited reimbursement offered by private payers, Medicaid, or Medicare.<sup>50</sup> Third, where there is no relationship between the patient in one state and a consulting physician in another state because the consulting physician has a relationship only with the originating physician, then such a consultation—potentially interstate and telemedical—arguably does not qualify as the “practice of medicine” and therefore does not require regulation.<sup>51</sup> Furthermore, many state licensing statutes included narrow exceptions to the requirement of licensure tailored to some geographically indeterminate physician-patient interactions.<sup>52</sup> Fourth (and related to the general lack of reimbursement), it may be that the majority of telemedicine initiatives have been state-funded and carried out by state actors—hardly politically feasible targets for even the most regulatory active or technophobic state medical boards.

Although traditional telemedicine was readily accepted without provoking change in existing state regulatory systems, more recent developments—particularly Internet-based changes—have resulted in

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(infrequent consultations).

49. See, e.g., *AMA President Talks to IBD About Guidelines for Information Technology Use*, June 3, 2002, <http://www.ama-assn.org/ama/pub/article/1615-6309.html> (reporting AMA President statement that “[t]here’s going to be cautious adoption of freestanding, online consultations. What’s clearly going to happen is an extension of telemedicine, where doctors are messaging between themselves.”).

50. See Edelstein, *supra* note 10.

51. See *Irvin v. Smith*, 31 P.3d 934 (Kan. 2001) (holding that a physician who gives an informal opinion at the request of a treating physician does not owe a duty to the patient).

52. See, e.g., KY. REV. STAT. ANN. § 311.560(2)(b)(1) (Michie 2003) (exempting from the state licensure requirement physicians who are licensed and reside in another state and whose only practice in Kentucky is infrequent consultation on medicine or osteopathy); see also 225 ILL. COMP. STAT. ANN. 60/49.5 (West 2003).

legislative reforms, changes in regulatory attitudes, and shifts in enforcement practices. There are several possible explanations for these changes. First, there is an atmosphere of distrust of all things Internet among medicine's professional leadership. Notwithstanding the patient safety movement's focus on technological solutions to medical and medication errors and patient demand for email contact with physicians, the Internet and related technologies are a source of frustration for most physicians. For example, patient access to under-regulated<sup>53</sup> direct-to-consumer (DTC) information provided by pharmaceutical company websites is viewed as suspect and adversely affecting physician-patient dialogue.<sup>54</sup> Further, many physicians deeply resent the federal e-health flagship initiative—the privacy regulations promulgated under the Health Insurance Portability and Accountability Act<sup>55</sup>—and view it as an expensive example of overreaching regulation.<sup>56</sup>

Second, technological innovations have allowed us to move past the paradigmatic telemedicine consult to more advanced direct telemedical examinations of the patient by the remote physician.<sup>57</sup> An IT technician or nurse may be the only “local” professional<sup>58</sup> sharing physical space with the patient. Moreover, on the near horizon is the increased deployment of telehome appliances that enable the patient to communicate directly with

53. See Christopher Rowland, *Lawmakers Assail FDA, Say Agency Fails To Get Tougher on Drug-ad Claims*, BOSTON GLOBE, Jan. 30, 2004, [http://www.boston.com/business/globe/articles/2004/01/30/lawmakers\\_assail\\_fda/](http://www.boston.com/business/globe/articles/2004/01/30/lawmakers_assail_fda/).

54. Physicians, many of whom feel that visits are already overly compressed and burdened by the requirements of managed care, complain that DTC advertising makes patients more difficult to deal with and make visits even more time-consuming. See SUSANNAH FOX & DEBORAH FALLOWS, PEW INTERNET & AMERICAN LIFE PROJECT, INTERNET HEALTH RESOURCES (2003) [hereinafter FOX & FALLOWS], [http://207.21.232.103/pdfs/PIP\\_Health\\_Report\\_July\\_2003.pdf](http://207.21.232.103/pdfs/PIP_Health_Report_July_2003.pdf); Paul R. Helft et al., *American Oncologists' Views of Internet Use by Cancer Patients: A Mail Survey of American Society of Clinical Oncology Members*, 21 J. CLINICAL ONCOLOGY 942 (2003).

55. Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. §§ 160, 164 (2003).

56. See, e.g., *South Carolina Med. Ass'n v. Thompson*, 327 F.3d 346 (4th Cir. 2003) (upholding HIPAA against impermissible delegation and vagueness challenges brought by medical associations and physicians); see also *infra* text accompanying note 253.

57. Some specialties, such as psychiatry, used these techniques earlier than other specialties and continue to utilize them more frequently. Similarly, certain sub-populations, such as those in correctional facilities, have been particularly likely to receive direct telemedical services. See, e.g., Kate Murphy, *Telemedicine Getting a Test in Efforts To Cut Costs of Treating Prisoners*, N.Y. TIMES, June 8, 1998, at D1.

58. See *infra* text accompanying note 496.



health providers through consumer-friendly interfaces; such appliances have no need for a “local” professional other than an IT technician to hook the device into the patient’s broadband connection or nursing home network. Such medical practices cannot be characterized as “consultations” and thus cannot gain cover from the established exceptions in the medical practice acts; from the perspective of state regulators, these telehealth innovations must be addressed in a more direct (and generally disfavored) manner.

Third, telemedicine has been caught in the crossfire between regulators and Internet prescribers.<sup>59</sup> Just as the regulation of cloning and harvesting of fetal and embryo tissue influences responsible stem cell research,<sup>60</sup> the regulatory attack on Internet prescribing likely chills telemedicine. A large number of states have rewritten their licensure rules to bring Internet prescribing within the importing state’s disciplinary ambit and, in the process, have added new definitions of telemedicine which impose state regulations on what heretofore were legally “safe” consulting relationships. For example, several jurisdictions have amended their licensing laws to specifically include “imported” electronic diagnosis or treatment.<sup>61</sup> Contemporary regulation of telemedicine, however, is anything but uniform. For example, the updated definitions of telemedicine in Arizona<sup>62</sup> and California<sup>63</sup> capture both intrastate and interstate consultations. In contrast, the Montana statute applies telemedicine-specific regulation only to interstate exchanges between physician and patient,<sup>64</sup> and the West Virginia definition of the “practice of

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59. Regulating the Internet certainly presents certain challenges: As I have argued elsewhere, “[The] lack of physicality, the decoupling of physician from jurisdiction-delimited practice, severely challenges state licensing systems that apply to healthcare professionals.” Terry, *supra* note 14, at 607. However, state regulators have responded in different ways; some have increased the enforcement of physician practice requirements and standards, while others have developed novel regulation of pharmacy practice. *See generally infra* Section II.C.

60. *See generally* Timothy Stoltzfus Jost, *Rights of Embryo and Fetus in Private Law*, 50 AM. J. COMP. L. 633, 644-45 (2002). However, California specifically distinguishes between disapproved tissue transactions, CAL. HEALTH & SAFETY CODE § 125117 (West 2004), and encouraged stem cell research, CAL. HEALTH & SAFETY CODE § 125115 (West 2004).

61. ALA. CODE § 34-24-501(a) (1975). The same definition is used by Mississippi, MISS. CODE ANN. § 73-25-34 (1998); Missouri, MO. REV. STAT. § 334.010 (2001); New Mexico, N.M. STAT. ANN. § 61-6-6 (Michie 2004); and Oregon, OR. REV. STAT. § 677.135 (2004).

62. ARIZ. REV. STAT. § 36-3601(2) (2003).

63. CAL. BUS. & PROF. CODE § 2290.5(a)(1) (West 2003).

64. MONT. CODE ANN. § 37-3-342 (2003).

telemedicine” is limited to diagnosis or treatment by out-of-state physicians.<sup>65</sup>

The assumption that cross-border telemedical consultations are exempt from regulation by an additional state board is also being challenged. For example, while the Alabama statute purports to still exclude consultations from regulation, this exemption is limited to uncompensated, informal consultations where the remote physician has not given a formal or written opinion.<sup>66</sup> The same state exempts physicians from the requirement of a telemedicine practice certificate (“special purpose license”) in emergency situations<sup>67</sup> or “on an irregular or infrequent basis.”<sup>68</sup>

The types of interactions the emerging telemedicine definitions seek to regulate differ among states. While the Arizona law applies broadly to all forms of technologically-mediated healthcare,<sup>69</sup> the California statute is limited to “real time (synchronous) or near real time (asynchronous) two-way transfer of medical data and information.”<sup>70</sup> The statute explicitly excludes telephone or email.<sup>71</sup> It is not immediately clear why regulators make distinctions based on the technologies employed or would disfavor closed (and likely secure) systems such as teleradiology or videoconferencing over open or public systems such as telephony. There is reason to suspect technophobia; in practice, stringent regulation of synchronous interactions disproportionately targets physicians employing sophisticated and secure technologies that are professionally appropriate.

Not content with tightening up their existing controls and reducing exemptions for telemedicine, states are targeting telemedicine and other

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65. W. VA. CODE § 30-3-13 (Michie 2003).

66. According to Alabama law,

this definition is not intended to include an informal consultation between a licensed physician located in this state and a physician located outside this state provided that the consultation is conducted without compensation to or the expectation of compensation to either physician and does not result in the formal rendering of a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient by the physician located outside the state.

ALA. CODE § 34-24-501(a)(3) (1975).

67. *Id.* § 34-24-505(a).

68. The statute defines the latter as one that “occurs less than 10 times in a calendar year or involves fewer than 10 patients in a calendar year or comprises less than one percent of the physician’s diagnostic or therapeutic practice.” *Id.* § 34-24-505(b).

69. ARIZ. REV. STAT. § 36-3601(2) (West 2003).

70. CAL. BUS. & PROF. CODE § 2290.5(a)(2) (West 2003).

71. *Id.* § 2290.5(a)(1).

models of technologically mediated care for additional regulation. For example, several states, including Alabama,<sup>72</sup> Minnesota,<sup>73</sup> Montana,<sup>74</sup> New Mexico,<sup>75</sup> and Ohio<sup>76</sup> require an out-of-state physician to apply for a specialty-specific telemedicine practice certificate. Another trend, exemplified by regulatory changes in Arizona,<sup>77</sup> California,<sup>78</sup> Kentucky,<sup>79</sup> Nebraska,<sup>80</sup> Oklahoma<sup>81</sup> Puerto Rico,<sup>82</sup> and Texas,<sup>83</sup> is to require telemedicine-specific consent and correlated record-keeping.<sup>84</sup> For example, California requires “verbal and written informed consent [including a] description of the potential risks, consequences, and benefits of telemedicine.”<sup>85</sup> Kentucky, among other states, emphasizes compliance with state and federal confidentiality and privacy laws.<sup>86</sup>

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72. ALA. CODE § 34-24-502 (1975).

73. MINN. STAT. § 147.032 (West 2003).

74. MONT. CODE ANN. § 37-3-343 (2003).

75. N.M. STAT. ANN. § 61-6-11-1 (Michie 2004).

76. OHIO REV. CODE ANN. § 4731.296 (Anderson 2003).

77. ARIZ. REV. STAT. § 36-3602 (West 2003).

78. CAL. BUS. & PROF. CODE § 2290.5 (West 2003).

79. KY. REV. STAT. ANN. § 311.5975(1)(a) (Michie 2001) (“A treating physician who provides or facilitates the use of telehealth shall ensure: . . . [t]hat the informed consent of the patient, or another appropriate person with authority to make the health care treatment decision for the patient, is obtained before services are provided through telehealth. . . .”).

80. NEB. REV. STAT. § 71-8505 (2002).

81. OKLA. STAT. ANN. TIT. 36, § 6804 (West 1999).

82. 20 P.R. LAWS ANN. § 6006 (2003).

83. Texas State Board of Medical Examiners, Rule 174.10, <http://www.tsbme.state.tx.us/rules/rules/174.htm>.

84. *See, e.g.*, ALA. CODE § 34-24-504 (1975) (“Any licensee licensed under the provision of this article shall comply with all laws, rules, and regulations governing the maintenance of patient medical records, including patient confidentiality requirements, regardless of the state where the medical records of any patient within this state are maintained.”). Not all states, however, apply these requirements to intrastate relationships. *See also* 36 OKLA. STAT. ANN. tit. 36, § 6804 (F)(G) (West 1999).

85. CAL. BUS. & PROF. CODE § 2290.5(c) (West 2003); *see also* CAL HEALTH & SAFETY CODE § 123149.5 (West 2004).

86. KY. REV. STAT. ANN. § 311.5975(1)(b) (Michie 2001) (“A treating physician who provides or facilitates the use of telehealth shall ensure . . . [t]hat the confidentiality of the patient’s medical information is maintained as required by this chapter and other applicable law. At a minimum, confidentiality shall be maintained through appropriate processes, practices, and technology as designated by the board and that conform to applicable federal law.”).

*C. Emerging Regulation of Internet Prescribing*

State legislatures or medical boards seem to favor three approaches to controlling Internet prescribing. First, some states rely on the regulatory changes that they have already made to accommodate telemedicine. Second, other states concentrate on the specifics of the physician-patient relationship, either by requiring a so-called "traditional" or "proper" relationship, or more transparently, by requiring face-to-face contact or prohibiting questionnaire-based prescribing. Third, some states have shifted their focus from physician to pharmacy regulation by concentrating on the product of an often out-of-state technologically-mediated relationship (i.e., the prescription) and seeking to control its in-state dispensing. Many states have adopted two or more of these approaches, creating overlapping and frequently confusing regulatory regimes.

Some states impose explicit new controls on prescribing by requiring an existing physician-patient relationship and a physical face-to-face examination prior to prescribing.<sup>87</sup> This requirement aims to eliminate "one-shot" transactions between Internet prescribers and patients where the interaction is the fulfillment of a single drug order (the previously noted opportunistic physician-patient relationship); it is also supposed to outlaw so-called questionnaire prescribing.<sup>88</sup>

Questionnaires are widely used by both illegal and marginally legal websites.<sup>89</sup> Typically, the questionnaire is a web-based form that purports to

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87. The California statute provides that "[p]rescribing, dispensing, or furnishing dangerous drugs . . . without a good faith prior examination and medical indication therefor, constitutes unprofessional conduct." CAL. BUS. & PROF. CODE § 2242(a) (West 2003). Arizona extends its definition of "[u]nprofessional conduct," other than in emergencies, to "[p]rescribing, dispensing or furnishing a prescription medication or a prescription-only device to a person if the licensee has not conducted a physical examination of that person or has not previously established a physician-patient relationship." ARIZ. STAT. §32-1854(51) (West 2003).

88. See Sana Siwolop, *Buying Your Pills Online May Save You Money, but Who's Selling Them?*, N.Y. TIMES, Sept. 29, 2002, at 3-10 ("According to the Federation of State Medical Boards, a professional group, only one state, Kentucky, has passed legislation that specifically prohibits prescriptions based only on online questionnaires, while 22 states, including New York, have rules that essentially require a physical exam before an online prescription can be filled.")

89. According to the National Center on Addiction and Substance Abuse (CASA), of the sites selling controlled prescription drugs on the Internet forty-five percent required no prescription or made no mention of it, forty-nine percent provided an online consultation in lieu of a prescription, but only six percent required a preexisting prescription. NAT'L

collect a health history and asks questions specific to the drug requested. The drug-related questions are usually based on information taken from the *Physicians' Desk Reference*.<sup>90</sup> The completed questionnaire is then transmitted for approval. This approval may well be placed in the hands of a physician licensed to practice medicine in the patient's home state, and the process that follows purports to be the functional equivalent of in-office or telephone prescribing. The suspicion, however, is that in most cases any "approval" is performed by contract ghost-writers of indeterminate licensure who rubber-stamp hundreds of such prescriptions per week.<sup>91</sup> In some cases, the "approval" seems to be omitted or automated, and the order is merely forwarded for fulfillment.

States are increasingly tightening their scrutiny of these practices. Some have chosen a statutory route that adds a gloss to its requirement of a "proper physician-patient relationship," taking the position that "an electronic, on-line, or telephonic evaluation by questionnaire is inadequate for the initial evaluation of the patient or for any follow-up evaluation."<sup>92</sup> At least one state seems to be relying on its medical board to issue rules<sup>93</sup> or guidance<sup>94</sup> that have a similar effect.

Regulatory amendments to control the prescribing practices of out-of-state physicians or automated pill-mills are ineffective without strong cross-

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CTR. ON ADDICTION AND SUBSTANCE ABUSE AT COLUMBIA, YOU'VE GOT DRUGS! PRESCRIPTION DRUG PUSHERS ON THE INTERNET 5 (2004), [http://209.208.151.183:8080/pdshopprov/files/you\\_ve\\_got\\_drugs.pdf](http://209.208.151.183:8080/pdshopprov/files/you_ve_got_drugs.pdf).

90. *Physicians' Desk Reference*, now in its fifty-eighth edition, is the standard prescription drug reference manual.

91. See, e.g., *United States v. Nelson*, 72 Fed. Appx. 837 (10th Cir. 2003). One doctor contacted by congressional investigators has admitted to writing 100,000 prescriptions for several Internet pharmacies over a two-year period. Typically he received \$2.50 to \$5 per prescription. He approved ninety-five percent of the drug applications sent to him, although the online pharmacy pre-screened out some applications. *N.J. Doctor's Rx on the Web Draws Scrutiny*, THE RECORD (Bergen County, NJ), Jan. 21, 2004, at A01; see also Gilbert M. Gaul, *Crossing Lines To Prescribe Online, Internet Pathologist Outmaneuvers State Medical Boards*, WASH. POST, Dec. 18, 2003, at A1 (discussing prescribing practices of Dr. Miles J. Jones and noting "Jones said he has written online prescriptions for more than 35,000 patients for netdr.com and its affiliated maleclinic.com. Nearly eight of every 10 customers have requested Viagra, the popular drug for treating erectile dysfunction. All but about 100 of the requests have been approved.").

92. KY. REV. STAT. STAT. §311.597(1)(e) (Michie 2003).

93. ALA. ADMIN. CODE §540-X-9-11 (1975).

94. See, e.g., Texas State Board of Medical Examiners, *Internet Prescribing Policy* (Dec. 8-11, 1999), <http://www.tsbme.state.tx.us/guidelines/ipp.htm> (last visited Apr. 16, 2004).

border enforcement mechanisms. Recognizing the practical difficulties of curtailing the activities of those outside their borders, several states have introduced a more indirect form of regulation that requires in-state pharmacists to verify that the prescriptions presented to them are written after physical (and hence for all practical purposes in-state) examinations.<sup>95</sup> Thus, some state rules now prohibit a pharmacist from dispensing a prescription drug if he “knows or should have known that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid patient-practitioner relationship.”<sup>96</sup>

Regulation is sure to escalate as illegal pill-mills learn to hide in cyberspace and, like pornographers and online casinos, move their physical businesses offshore. Regulators will be forced to “follow the money” as they have in pornography and gambling cases and hope for the cooperation of credit card companies,<sup>97</sup> other financial intermediaries,<sup>98</sup> and shipping companies<sup>99</sup> while legitimate businesses bring pressure on infomediaries such as search engines to de-list illegal operations.<sup>100</sup>

95. See, e.g., CAL. BUS. & PROF. CODE § 4067; see also *id.* § 2242.1(b); VA. CODE ANN. § 54.1-3303(A)(B) (Michie 2004).

96. TEX. ADMIN. CODE §§ 291.34, 291.36 (West 2004). California imposes a similar rule and backs it with fines up to \$25,000 per occurrence. CAL. BUS. & PROF. CODE § 4067; see also *id.* § 2242.1(b); VA. CODE ANN. § 54.1-3303(A)(B) (Michie 2004).

97. See, e.g., Associated Press, *MasterCard Sets Rules for Online Gambling To Settle Lawsuit* (July 14, 1999), [http://standup.quiknet.com/news/1999/ap\\_1999\\_july\\_14.html](http://standup.quiknet.com/news/1999/ap_1999_july_14.html); Press Release, MasterCard Voices Support for Measures To Stop the Use of Payment Cards for Illegal Internet Gambling (Mar. 17, 2003), <http://www.mastercardintl.com/cgi-bin/newsroom.cgi?id=708>.

98. See, e.g., CNET News.com, *PayPal Turns Off the Red Light* (Apr. 30, 2003), at <http://news.com.com/2100-1017-999002.html> (discussing decision by PayPal’s revised policy on processing payment for adult material). PayPal already places limits on payments for prescription drugs, PayPal, at *PayPal Prescription Drugs and Devices Policy*, [http://www.paypal.com/cgi-bin/webscr?cmd=p/gen/ua/use/index\\_frame-outside&ced=prescript\\_drugs](http://www.paypal.com/cgi-bin/webscr?cmd=p/gen/ua/use/index_frame-outside&ced=prescript_drugs) (last visited July 29, 2004).

99. See, e.g., Gilbert M. Gaul & Mary Pat Flaherty, *Google To Limit Some Drug Ads, Web Giants Asked To Help Discourage Illicit Online Pharmacies*, WASH. POST, Dec. 1, 2003, at A1 [hereinafter Gaul & Flaherty, *Google To Limit*]; Gilbert M. Gaul & Mary Pat Flaherty, *Firms Pressed on Internet Drugs; Senate Panel Writes to Credit Card Companies, Shippers*, WASH. POST, Dec. 10, 2003, at A04 [hereinafter Gaul & Flaherty, *Firms Pressed*]; Rick Brooks, *FedEx and UPS Say They Shun Parcels Containing Illicit Drugs*, WALL ST. J., Jan. 9, 2004, at A8.

100. See, e.g., CNET News.com, *Search Engines Face Drug Test* (Nov. 10, 2003), at [http://rss.com.com/2100-1024\\_3-5105044.html?tag=prntfr](http://rss.com.com/2100-1024_3-5105044.html?tag=prntfr). Google, Yahoo, and MSN have announced plans to refuse advertising from unlicensed pharmacies. Google also will prevent the names of certain controlled drugs from appearing in the results of keyword

### *D. Regulating Online Dispensing*

Illegal online dispensing is an extension of the previously discussed Internet prescribing. Since few Internet prescribers have their own distribution business, they pass the prescriptions they write onto a subset of legally suspect fulfillment pharmacies usually based in the United States. Much of domestic Internet prescribing is driven by patients seeking drugs, including controlled substances, which their physicians will not prescribe or that are “lifestyle” drugs that patients do not want to publicly request. In most cases, patients are prepared to pay at least as much for the drugs as they would at a local or legal Internet pharmacy. Simultaneously, a new model of international fulfillment is flourishing that promises to deliver considerable savings over U.S.-sourced drugs by importing “legend drugs”<sup>101</sup> from non-U.S. sources such as Canada.

#### *1. Domestic Drug Distribution*

The Food and Drug Administration’s (FDA) process for new drug approval (NDA) and the Drug Enforcement Agency’s (DEA) controlled substances policies underpin domestic drug availability. Thereafter, the core operational rules on domestic distribution are found in state pharmacy statutes and regulations. The relationship between state and federal regulators has generally been harmonious,<sup>102</sup> with the states usually happy to rely on their better funded federal counterparts to provide enforcement.

State regulation of drug distribution has both negative and positive aspects. State law generally prohibits anyone in the chain of distribution from purchasing or receiving prescription drugs from anyone other than a licensed person.<sup>103</sup> Having reinforced the retail prescription drug monopoly of pharmacies, state law then regulates the practice of pharmacy through the traditional tools of licensure and discipline. Assuming compliance with the FDA, DEA, and state licensing board regulations, the

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searching. Gaul & Flaherty, *Google To Limit*, *supra* note 99.

101. “Legend drugs” are those that, under Section 503(b) of the Federal Food, Drug, and Cosmetic Act, cannot be dispensed without a prescription.

102. There are some exceptions to the general harmony, such as occasional differences over issues such as medical marijuana. *Cf. Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002).

103. *See, e.g.*, N.D. CENT. CODE § 43-15.1-02 (2001) (“No person may knowingly purchase or receive any prescription drug from any source other than a wholesale drug distributor, manufacturer, pharmacy distributor, pharmacy, or other person licensed pursuant to the laws of this state except where otherwise provided.”).

growth of technology in prescription fulfillment affects a local pharmacy in two situations. First, and beyond the reach of this Article, technology facilitates the disintermediation of pharmacists through a combination of technology and lower-paid pharmacy technicians and so sharpens an emerging scope of practice issue. Second, local pharmacists increasingly face regulation on their fulfillment of out-of-state prescriptions written by Internet-based physicians.<sup>104</sup> However, it is worth mentioning that states have successfully regulated pharmacy distribution located outside their borders for several decades.

State pharmacy law addressed issues concerning out-of-state pharmacies long before the growth of Internet prescribing. Mail-order dispensing is at least a century old and involves hundreds of thousands of deliveries per year.<sup>105</sup> Mail-order pharmacies are frequently subject to regulations in importing states,<sup>106</sup> and even though regulators track down the occasional miscreants, mail-order fulfillment is relatively uncontroversial. Mail-order pharmacies and national pharmacy chains are large-volume businesses and so likely possess the resources to absorb multiple licensing costs. While the primary concern of state pharmacy regulation is distribution to consumers, some states regulate other participants in the distribution chain, including out-of-state wholesalers and distributors.<sup>107</sup>

The states have sought to extend their mail-order model of required licensure to interstate Internet prescribing. As with mail-order models, large e-pharmacies or click-and-brick operations can absorb the costs of multiple licensure. States frequently prosecute or enjoin out-of-state pill-mills, but they are often hindered by insufficient enforcement resources and, frequently, by the inadequacy of their own regulations. Increasingly,

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104. Some border states allow the "importation" of a prescription, allowing their pharmacists to fill prescriptions written by, for example, Canadian or Mexican doctors. *See, e.g.,* ARIZ. REV. STAT. § 32-1969 (2003).

105. *See Nat'l Pharms. v. De Melecio*, 221 F.3d 235, 237 (1st Cir. 2000).

106. *Nat'l Pharms.*, 221 F.3d at 242; *see also Pharm. Mfrs. Ass'n v. New Mexico Bd. of Pharmacy*, 525 P.2d 931 (N.M. Ct. App. 1974) (upholding state pharmacy board regulation of out-of-state manufacturers and distributors). For example, the North Dakota statute provides:

Any pharmacy operating outside the state which ships, mails, or delivers in any manner a dispensed prescription drug or legend drug into North Dakota shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state law and rules of the board.

N.D. CENT. CODE § 43-15-34.1 (2001).

107. *See, e.g.,* N.D. CENT. CODE, § 43-15.1-05 (2001).



states are re-vamping their pharmacy rules to deal specifically with the latest generation of Internet businesses.<sup>108</sup> For example, the Arkansas Internet Prescription Consumer Protection Act 2001,<sup>109</sup> which updates the traditional prohibitions on unlicensed dispensing to specifically include Internet operations,<sup>110</sup> requires the disclosure of the identity of and contact information for the business,<sup>111</sup> and outlaws the disclaimers and waivers commonly found on Internet prescribing and dispensing sites.<sup>112</sup> The Texas statute, perhaps conscious of VIPPS efforts to validate licensure,<sup>113</sup> requires that e-pharmacies link to the Texas Pharmacy Board website.<sup>114</sup>

## 2. Cross Border Drug Distribution

While some illegal prescribing operations are moving offshore, the scenario of Internet prescribing remains a primarily domestic, interstate paradigm. In contrast, Internet dispensing is increasingly an international phenomenon involving many regulatory actors and a complex legal landscape.<sup>115</sup> Over the last few years, direct personal importation of pharmaceuticals into the United States has shown explosive growth; approximately ten million U.S. citizens per year transport drugs over land borders,<sup>116</sup> and approximately two million shipments of foreign-sourced prescription drugs entered the United States in 2002, double the number in 2001.<sup>117</sup>

The importation of drugs into the United States is regulated by a combination of federal laws and policies enforced by the DEA and FDA in conjunction with state pharmacy and controlled substance laws. Federal authorities have traditionally taken the enforcement lead, in part because

108. See, e.g., ILL. COMP. STAT. 85/16a (1998); IND. CODE ANN. § 25-26-18-1 (Supp. 2003); NEV. REV. STAT. ANN. §§ 453.3618, 453.3625, 453.3638, 453.3643, 453.3648, 639.00865, 639.012; 639.2328 (2000).

109. ARK. CODE ANN. §17-92-1001 to -1007 (2002).

110. *Id.* § 17-92-1004.

111. *Id.* § 17-92-1005.

112. *Id.* § 17-92-1006.

113. See *infra* note 374 and accompanying text.

114. TEX. OCC. CODE ANN. § 562.1045 (Vernon 2004).

115. See, e.g., *Customs Confiscates Viagra Ordered over the Internet: Hundreds of Finns Order Prescription Drugs Unaware That It Is Illegal*, HELSINKI SANOMAT, Oct. 23, 2002, <http://www.helsinki-hs.net/news.asp?id=20021023IE4>.

116. Mary Pat Flaherty & Gilbert M. Gaul, *Millions of Americans Look Outside U.S. for Drugs*, WASH. POST, Oct. 23, 2003, at A1.

117. *A New Source for Discount Prescriptions*, N.Y. TIMES, Dec. 26, 2002, at A36.

of their greater resources but also because suspect drugs are usually discovered by the United States Customs Service, the agency charged with enforcing the drug laws and policies of the DEA and FDA.

According to the Federal Food, Drug, and Cosmetic Act (FDCA), “[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug.”<sup>118</sup> Thus, the central plank of the FDA’s prohibition of non-U.S. sourced prescription drugs is that they lack approval under the NDA process. The FDA’s position is that this prohibition extends beyond foreign versions to also include a grey market version of an approved drug, because the latter is unlikely to comply with all the technical information required for domestic approval, such as source of ingredients, place of manufacture, labeling and packaging of containers.<sup>119</sup>

More controversially, regulators view reimported drugs as unapproved on the basis that they will comply with their destination market’s labeling and packaging requirements rather than those necessary in the United States.<sup>120</sup> In addition, the FDA takes the speculative position that grey market or reimported drugs are likely to be mislabeled<sup>121</sup> or dispensed without a prescription.<sup>122</sup> The agency may be on firmer ground in relying on legislation that grants the sole right of reimportation to U.S. manufacturers.<sup>123</sup>

Federal law prohibits breach of these FDCA provisions.<sup>124</sup> The

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118. 21 U.S.C. § 355(a) (2000).

119. *See* 21 C.F.R. § 314.50 (2003) (listing drug application requirements).

120. *See, e.g., id.* § 314.50(c)(2)(i).

121. 21 U.S.C. § 353(b)(2) (2000).

122. *See id.* § 353(b)(1). Also note that the exception to § 352 is inapplicable to mail order drugs. *Id.* § 353(b)(2).

123. *Id.* § 381(d)(1) (“[N]o drug subject to section 353(b) of this title . . . which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.”); *see also* Warning Letter from David J. Horowitz, Director, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration to Harry Lee Jones, Store Manager, Rx Depot, Inc. (Mar. 21, 2003) [hereinafter Warning Letter from David J. Horowitz], [http://www.fda.gov/foi/warning\\_letters/g3888d.htm](http://www.fda.gov/foi/warning_letters/g3888d.htm); Letter from William K. Hubbard, Associate Commissioner for Policy and Planning FDA to Robert P. Lombardi, The Kullman Firm (Feb. 12, 2003) [hereinafter Letter from William K. Hubbard], <http://www.fda.gov/ora/import/kullman.htm>.

124. 21 U.S.C. § 331(a), (d), (t) (2000).

prohibition is applicable to both interstate and intrastate traffic.<sup>125</sup> If the drug is a controlled substance it is further subject to regulation by the DEA under the Controlled Substances Act of 1970 (CSA).<sup>126</sup> Operationally, state pharmacy and other drug laws enter the regulatory mix because they frequently prohibit possession or trafficking of drugs without a U.S. prescription, or of drugs that do not comply with the federal act.<sup>127</sup>

There are sound policy reasons for allowing some level of personal importation of pharmaceuticals into the United States. First, as a practical matter, residents and visitors will enter the United States carrying drugs prescribed outside the United States or even within the United States prior to outbound travel. In addition to the dangers it would pose to a traveler's health, policing a rigid non-possession rule would be as nonsensical as it would be unenforceable. Second, there is a small but significant traffic in persons leaving the United States for treatment not otherwise available in the United States. It would be punitive to deny, upon the patient's return to the United States, pharmaceuticals related to the treatment. Third, the high expense of travel and the small amounts of prescription drugs that people can physically bring with them imposes high transaction costs on patients, thus minimizing risks of diversion. Fourth, many if not most of the drugs personally presented at United States borders are approved for sale in the United States in some form or another, thus minimizing safety-related risks.

These policies are effectuated by federal rules and policies that allow a limited level of cross-border pharmaceutical traffic. The CSA, for example, has a limited personal importation exception that allows individuals to bring a controlled substance with them if: 1) the substance is found in one of the approved "schedules," 2) the substance is in its original container, 3) a declaration is made to the United States Customs Service, and 4) use of such substance is permitted by federal and state laws.<sup>128</sup>

Concerns about the introduction of large amounts of controlled substances, particularly over the border with Mexico, led to the tightening of this exception by the Controlled Substances Trafficking Prohibition Act of 1998 (CSTPA). The act states that a U.S. resident may not enter the U.S. through an international land border with more than fifty dosage units of a controlled substance unless the individual possesses a valid prescription

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125. *See, e.g., White v. United States*, 399 F.2d 813 (8th Cir. 1968).

126. Controlled Substances Act (CSA), 21 U.S.C. §§ 801-971 (2000).

127. *See, e.g., ARIZ. REV. STAT. § 32-1962(A)* (2002).

128. 21 U.S.C. § 956(a) (2000).

issued by a practitioner in accordance with federal and state law.<sup>129</sup>

The CSA exemption clearly assumes that the drugs are in the possession of a traveler.<sup>130</sup> The FDCA Guidance implies personal possession by excluding commercial and promotional shipments.<sup>131</sup> To determine if a shipment is commercial or promotional, the Guidance suggests looking at “the type of product, accompanying literature, size, value, and/or destination of the shipment.”<sup>132</sup> The Guidance also states that non-commercial shipments generally include products that are: “personally carried, shipped by a personal non-commercial representative of a co-

129. *Id.* § 956(a)(2). The CSTPA has been the source of much confusion, some of which derives from the misrepresentation seeded by parallel importers. On its face, the legislation does not exempt amounts below fifty dosage units but uses that quantity as a ceiling. *Id.* Nonetheless, the statutory phrase “50 dosage units,” is cited frequently by importers as exempting all pharmaceutical imports up to that amount. *See, e.g.,* Nancy A. Melville, *U.S. Health Experts Say Caveat Emptor on South-of-Border Prescription Drugs*, at <http://www.roadandtravel.com/health/prescriptiondrugs.htm> (last visited July 10, 2004). The DEA, however, has frequently disputed this interpretation. *See, e.g.,* *Hearing Before the House Comm. on Energy and Commerce Subcomm. on Oversight and Investigations*, 107th Cong. (2001) (statement of Laura M. Nagel, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration), <http://www.usdoj.gov/dea/pubs/cngrtest/ct060701.htm> (“This does *not* mean that any U.S. resident may enter the United States with up to 50 dosage units of a particular controlled substance ‘no questions asked.’ Rather, the resident must satisfy all the requirements set forth in 21 C.F.R. 1301.26. States may impose additional requirements as well.”). There is no personal importation exception in the FDCA. The FDA, however, has issued enforcement guidelines that create a de facto exemption and answers the issue (or at least the federal issue) left hanging by the Controlled Substances regulations. *See* 21 C.F.R. § 1301.26 (2003) (“Any individual who has in his/her possession a controlled substance . . . may enter or depart the United States with such substance . . . providing . . . [t]he importation of the controlled substance for personal medical use is authorized or permitted under other Federal laws and state law.”). Described as “guidance” to its own personnel, the FDA applies this “exemption” when “the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user.” FDA/ORA, Regulatory Procedures Manual, [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9pers.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html) (discussing personal importations). The agency emphasizes that “[a]lthough FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.” *Id.*

130. 21 C.F.R. § 1301.26 (2003) (“Any individual who has in his/her possession a controlled substance . . . may enter or depart the United States . . .”).

131. Marvin A. Blumberg, *Information on Importation of Drugs, Prepared by the Division of Import Operations and Policy*, FDA, U.S. Food & Drug Administration, <http://www.fda.gov/ora/import/pipinfo.htm> (Apr. 3, 1998).

132. *Id.*

signee, or shipped from a foreign medical center where person has undergone treatment.”<sup>133</sup>

Because the guidance stresses that there is no particular magic in a U.S. prescription or a foreign prescription, the apparent keys to FDA approval (i.e., non-enforcement) are personal use of a drug otherwise not available and evidence of medical supervision.<sup>134</sup>

Crucially, the FDA denies that its de facto exemption applies to grey market or reimported drugs whether personally or commercially imported. According to the FDA,

foreign-made chemical versions of drugs available in the U.S. are not intended to be covered by the policy. . . . FDA cannot assure that such products have been properly manufactured and are effective; therefore . . . their use would present an unreasonable risk . . . unless the person seeking importation could establish that the drugs were needed to refill a prescription while traveling . . . .<sup>135</sup>

Despite this relatively clear regulatory position, importation drug sites routinely and inaccurately cite this Guidance (albeit usually without specific identification) as permitting the commercial importation of a ninety-day supply of drugs.<sup>136</sup>

### *3. The Canada-United States Connection*

The movement of grey market and reimported drugs over the Canadian-U.S. border predates Internet dispensing. For example, there are old press reports of U.S. retirees taking buses across the border and stocking up on prescription drugs.<sup>137</sup> Current economic conditions encourage the traffic: The Canadian government closely controls drug prices, and the weakness of the Canadian dollar favors U.S. purchasers. Dr. Alan Sager of Boston University has estimated that paying Canadian prices

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133. *Id.*

134. *See id.*

135. *Id.*

136. GetMeds Direct, at <http://www.getmedsdirect.com> (last visited May 29, 2003) (“Did you know U.S. law permits you to order a 60-90 day personal supply of Medications from International Pharmacies?”).

137. *See, e.g.,* Sarah Lueck, *Senators Push Drug-Reimportation Bill*, WALL ST. J., June 3, 2002, at A4; *see also* Alexander Calhoun, *Get on the Bus: Extreme Answers to Prescription Drug Costs*, CHRISTIAN SCIENCE MONITOR, Apr. 18, 2000, at <http://csmweb2.emcweb.com/durable/2000/04/18/p3s1.htm>; Randi Hunter Epstein, *Some Retirees Look Abroad for Prescription Drugs*, N.Y. TIMES, Sept. 24, 2002, at F5.

for U.S. prescription drugs would result in savings of \$38.4 billion per annum, a figure which underpins much of the debate over the Canadian connection.<sup>138</sup> A congressional estimate is even more optimistic: "Allowing open pharmaceutical markets could save American consumers at least \$635 billion of their own money each year."<sup>139</sup>

By early 2003, there were approximately one hundred and fifty Canadian e-pharmacies exporting price controlled drugs to the United States.<sup>140</sup> Unlike the practices of the domestic Internet prescribing and dispensing sites frequently pursued by regulators, potential customers of Canadian e-pharmacies typically are required to furnish copies of a prescription written by their U.S. physician. Some of these businesses claim that licensed Canadian physicians will perform the prescribing, and the prescriptions will be fulfilled by licensed Canadian pharmacies.<sup>141</sup> In fact, that is generally the case, although not without some legal gymnastics north of the border. For example, Manitoba, home to about one-third of the e-pharmacies, requires that a Canadian licensed physician co-sign the prescription but the pharmacies have to use out-of-province physicians because Manitoba physicians have been threatened with disciplinary action if they become involved.<sup>142</sup>

True to the ideals of web-commerce, there has been a growth of infomediaries that provide licensure information and price comparisons for U.S. and Canadian sources of prescription drugs.<sup>143</sup> A relatively new twist in the U.S.-Canada traffic has been the proliferation of U.S.-based intermediaries. These small bricks-and-mortar stores, frequently established in locations with a large elderly population, assist patients who

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138. See, e.g., Markian Hawryluk, *Drugs Without Borders: When Prescription Drugs Go over the Line*, AMNEWS, Oct. 22/29, 2001, at [http://www.ama-assn.org/sci-pubs/amnews/pick\\_01/gvsa1022.htm](http://www.ama-assn.org/sci-pubs/amnews/pick_01/gvsa1022.htm) (last visited Apr. 17, 2004).

139. Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. § 2(5).

140. See Joel Baglole, *Canada's Southern Drug*, WALL ST. J., Mar. 31, 2003, at B3.

141. See Joel Baglole, *Manitoba Fills Niche for Affordable Drugs*, WALL ST. J., Oct. 10, 2002, at B3.

142. *Plug May Be Pulled on On-line Pharmacies*, GLOBE & MAIL, Dec. 15, 2003, available at <http://www.globeandmail.com/servlet/ArticleNews/front/RTGAM/20021215/wpharm1215a/Front/homeBN/breakingnews> (last visited Apr. 13, 2004).

143. See, e.g., Pharmacy Checker.com, at <http://www.pharmacychecker.com> (last visited Apr. 13, 2004). United Health Alliance, a Vermont-based non-profit, is among the most visible. It lobbies for lower prescription drug costs and through its "Medicine Assist" program provides pricing and ordering information from Canadian e-pharmacies. See United Health Alliance, at <http://www.unitedhealthalliance.com> (last visited Apr. 13, 2004).

are less likely to be Internet savvy and may have difficulty filing out the forms.<sup>144</sup> The intermediaries take prescription requests from U.S. patients and transmit them to Canadian drugstores for direct fulfillment. The drugs are then supplied via mail to the patients in the United States, with the intermediary collecting a referral fee or commission on the sale.<sup>145</sup> A number of web-based businesses offer similar services.<sup>146</sup>

Although the amounts involved are modest, approximately \$700 million in annual Canadian e-pharmacy sales to the United States<sup>147</sup> compared to the overall \$150 billion U.S. pharmaceuticals market, U.S.-based pharmaceutical companies have become increasingly wary of this developing distribution channel.<sup>148</sup> Their attention seems to have become particularly focused after the United Health Group Inc., which insures nearly 100,000 AARP members, agreed to reimburse clients for prescriptions filled abroad. Pharmaceutical interests in the United States have also lobbied against legislation permitting drug reimportation on the basis that it would increase the likelihood of counterfeit, contaminated, or illegal drugs coming into the United States.<sup>149</sup>

This "quality" theme has underpinned the FDA's reaction to the Canadian connection. The alleged fear of the FDA is that the drugs are coming from some other country and simply passing through Canada.<sup>150</sup>

144. *Buying Drugs via Canada Gets Tougher*, SEATTLE TIMES, May 29, 2003, at A1.

145. *A New Source for Discount Prescriptions*, N.Y. TIMES, Dec. 26, 2002, at A36.

146. See, e.g., Canadian Meds USA, at <http://www.canadianmedsusa.com> (last visited Apr. 13, 2004); *Denver-based Web Site Helps Consumers Buy Cheaper Medications*, SiliconValley.com, at <http://www.siliconvalley.com/mld/siliconvalleynews/editorial/3541606.htm?template=> (June 25, 2002).

147. Tedeschi, *supra* note 24. Some estimates project the number at \$800 million to \$1 billion for 2003. See *Once Just a Trickle, Canada's Rx Drugs Pouring into USA*, USA TODAY, Oct. 7, 2003, at A1 [hereinafter *Once Just a Trickle*]; *U.S. Targets Internet Pharmacies, Health Canada Co-operating with U.S. Authorities*, NAT'L POST, Nov. 11, 2003, at <http://medical.marijuana.com/article.php?sid=7843>.

148. See Joel Baglole, *Getting the Gray Out: Canadian and U.S. Regulators Are Looking To Impose Order on the Sale of Cheap Online Drugs*, WALL ST. J., Feb. 11, 2003, at R6.

149. See, e.g., National Association of Chain Drug Stores News Release, National Association of Chain Drug Stores Joins Pharmacists in Endorsing the Cross-Border Communiqué Opposing Illegal Importation of Prescription Drugs (May 13, 2003), <http://www.nacds.org/wmspage.cfm?parml=3028>; see also Lueck, *supra* note 137.

150. Michelle Meadows, *Imported Drugs Raise Safety Concerns*, FDA CONSUMER MAG., Sept.-Oct. 2002, [http://www.fda.gov/fdac/features/2002/502\\_import.html](http://www.fda.gov/fdac/features/2002/502_import.html). The FDA currently has a task force working on counterfeit drugs and their impact on the U.S. distribution system. See FOOD & DRUG ADMIN., COUNTERFEIT DRUG TASK FORCE INTERIM REPORT (2003), [http://www.fda.gov/oc/initiatives/counterfeit/report/interim\\_report.html](http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html).

The sensitive question is whether U.S. (FDA) drug regulation is significantly superior to that found north of the border.<sup>151</sup> Health Canada's Therapeutic Products Directorate (TPD)<sup>152</sup> performs drug approvals under the Food and Drug Regulations made under the Canadian Food and Drugs Act.<sup>153</sup> The fact that Canada has a drug approval regulatory system that places a value on quality similar to that of the FDA continues to add its share of embarrassment to the dispute. In May 2003, a published report suggested that the quality argument would be preempted because the TPD would take responsibility for the safety of drugs reimported into the United States.<sup>154</sup> Further discussions between the governments led to a clarification to the effect that the Canadian government made no such guarantee;<sup>155</sup> subsequently, Health Canada offered to assist with enforcement.<sup>156</sup>

There are other reasons why dealing with the Canadian connection is considerably more difficult than typical regulatory policies and enforcement actions aimed at unlawful or marginally lawful domestic distributors. First, the traffic does not generally include controlled substances, depriving regulators of their traditional moral imperative. Second, the pharmaceuticals involved tend not to be lifestyle drugs, but rather life-sustaining or long-term maintenance drugs favored by seniors. Third, the practical difficulties of closing down the Canadian channel are immense. Huge numbers of suspect packages are crossing the border daily, rendering enforcement impractical. And, even if U.S.-based intermediary storefronts were closed, the bus trips by seniors across borders would

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151. According to William Hubbard, FDA associate commissioner, "My own 90-year-old mother cannot afford her drugs. . . . I know that. But nobody made FDA the drug-price-and-safety administration. They just made us the drug-safety guys. Our mission is not to establish prices of drugs, only to make sure they are safe." *U.S. Moves To Shut Companies Selling Imported Drugs*, HEALTH DAY, Sept. 11, 2003, at <http://www.healthcentral.com/news/NewsFullText.cfm?id=515064>.

152. Health Canada, Therapeutic Products Directorate, at [http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/aboutus\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/aboutus_e.html) (last visited Apr. 19, 2004).

153. Food and Drugs Act, R.S.C., ch. F-27, § 1 (1985) (Can.).

154. Marc Kaufman, *Canada To Guarantee Imported Medicine*, WASH. POST, May 8, 2003, at A6.

155. Marc Kaufman, *Canadian Drug Position Misinterpreted*, WASH. POST, May 26, 2003, at A11.

156. *FDA Seeks Help To Enforce Drug Laws; Health Canada Pledges Co-operation*, CANADIAN PRESS, Oct. 21, 2003; *U.S. Targets Internet Pharmacies, Health Canada Co-operating with U.S. Authorities*, NAT'L POST, Nov. 11, 2003, at A1.



continue<sup>157</sup> and the storefronts likely would be replaced by less formal channels, such as “Tupperware”-style parties.<sup>158</sup>

It is the politicization of the issue that creates particular challenges. Decreasing the cost of prescription drugs is a broadly-held political goal. The elderly population that tends to face the most difficulty in affording their drugs is electorally-significant and well-represented by lobbyists. While the media is happy to display its mock indignation at web-supplied Viagra, coverage of the enforcement of the reimportation prohibition against a U.S. senior and AARP member struggling to pay her escalating drug bill for life-sustaining medications is far more negative.<sup>159</sup>

In January 2003, the pharmaceutical multinational GlaxoSmithKline (GSK) increased monitoring of Canadian sales and threatened to cut off supplies to Canadian pharmacies that shipped to U.S. patients.<sup>160</sup> Canadian pharmacies and U.S. patient groups responded by urging a boycott of GSK products.<sup>161</sup> The Canadian Competition Bureau launched a brief investigation, but found no evidence that GSK was breaching the country’s antitrust laws.<sup>162</sup> In August 2003, Pfizer joined the other major drug manufacturers in requiring exporting Canadian pharmacies to buy supplies dictated by Canadian demand direct from Pfizer rather than from wholesalers.<sup>163</sup> Pfizer also requires its wholesale distributors to report orders

157. See *Once Just a Trickle*, *supra* note 147.

158. Gardiner Harris, *Canada Fills U.S. Prescriptions Under the Counter*, N.Y. TIMES, June 4, 2003, at A1.

159. The poster “children” of the drug reimportation fight are Ray and Gaylee Andrews of Elk Grove Village, Illinois. The two seventy-four year-olds spend \$800 to \$1,000 a month to buy prescriptions and have filed suit against HHS and the FDA mounting an equal protection challenge on the FDCA. Robert Pear, *U.S. To Study Importing Canada Drugs*, N.Y. TIMES, Feb. 26, 2004, at A16.

160. Press Release, GlaxoSmithKline Acts To Prevent Illegal, Potentially Unsafe Imports of Prescription Drugs (Jan. 21, 2003), *available at* [http://www.gsk.com/press\\_archive/press\\_01212003.htm](http://www.gsk.com/press_archive/press_01212003.htm); Sarah Lueck & Joel Baglole, *Glaxo Warns Canadian Clients Against Drug Sales to the U.S.*, WALL ST. J., Jan. 13, 2003, at B4.

161. See Julie Appleby, *Canadian Druggists Mobilize Against Glaxo*, USA TODAY, Feb. 5, 2003, at 1B.

162. Press Release, Competition Bureau, Competition Bureau Responds to Complaints Regarding Supply of Canadian-Based Internet Pharmacies (Mar. 21, 2003), <http://strategis.ic.gc.ca/epic/internet/incb-bc.nsf/en/ct02528e.html>.

163. Scott Hensley & Anna Wilde Mathews, *Pfizer Warning May Curb Drugs from Canada*, WALL ST. J., Aug. 7, 2003, at A2. A company spokesman stated “The objective of us having more customers as direct clients is for us to better enforce our terms of sale which are that our products are only to be sold in Canada for Canadian patients and that they are not for export.” Jane Taber, *Pfizer Takes Aim at Resale of Drugs*, GLOBE & MAIL, Aug. 7, 2003, at

from individual drugstores and requires them to seek approval before selling large amounts to any pharmacy or any amounts to new customers.<sup>164</sup> With the drug companies strangling the supply chain, Canadian pharmacies are being forced to buy the surplus supplies of other Canadian pharmacies or through intermediaries<sup>165</sup> and pass the increased costs onto U.S. consumers. At the same time, both individual pharmaceutical companies and their trade group increased their spending on lobbying against reimportation and other congressional threats to their price structures.<sup>166</sup>

The FDA signaled its intention to crack down on U.S.-Canada prescription drug traffic in February 2003.<sup>167</sup> In March 2003, the FDA's Office of Compliance sent out its first warning notice to a U.S.-based storefront, apparently an Arkansas affiliate or agent of a Manitoba pharmacy.<sup>168</sup> The FDA took the position that "almost every time an individual or business ships a prescription drug from Canada to a U.S. consumer, the individual or business shipping the drug violates the [FDCA]. Moreover, individuals and businesses, such as Rx Depot . . . and its responsible personnel, that cause those shipments also violate the Act."<sup>169</sup> The FDA reiterated its position in a letter to CanadianDiscountDrugs, an Alabama-based intermediary.<sup>170</sup> Subsequently,

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<http://globeandmail.com/servlet/story/RTGAM.20030807.wxudrugn0807/BNstory/Business/>; see also Tom Cohen, *Canada's Internet Pharmacies Hurting from Industry Steps To Halt U.S. Sales*, MERCURY NEWS, Aug. 29, 2003, <http://www.detnews/2003/health/0308/31/health-258099.htm>.

164. Bernard Simon, *Pfizer Moves To Try To Stop Drugs from Canada*, N.Y. TIMES, Jan. 14, 2004, at W1.

165. See Mark Heinzl & Tomsin Carlisle, *Canadian Pharmacies vs. Big Drug Makers*, WALL ST. J., Aug. 12, 2003, at D4; see also Cohen, *supra* note 163.

166. *Drug Group Spent \$8.5 Million Lobbying Against Importation*, PHILA. INQUIRER, Oct. 13, 2003.

167. See Thomas A. Burton, *The FDA Begins Cracking Down on Cheaper Drugs from Canada*, WALL ST. J., Mar. 12, 2003, at A1; Letter from William K. Horowitz, *supra* note 123.

168. See Warning Letter from David J. Horowitz, *supra* note 123; see also Jeff Gottlieb, *Stores Selling Drugs from Canada Thrive*, L.A. TIMES, Mar. 24, 2003, at 2-1.

169. Warning Letter from David J. Horowitz, *supra* note 123; see also Press Release, Food & Drug Admin., FDA Collaborates with Arkansas State Board of Pharmacy in Enforcement Action Against Storefront Obtaining Unapproved Drugs from Canada (Mar. 21, 2003), <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00882.html>.

170. Letter from David J. Horowitz, Director, Office of Compliance, Food & Drug Administration to Principals in CanadianDiscountDrugs (June 30, 2003), [http://www.nacds.org/user-assets/PDF\\_files/FDA\\_Letter\\_Canadian\\_Discount\\_Drugs\\_AL.pdf](http://www.nacds.org/user-assets/PDF_files/FDA_Letter_Canadian_Discount_Drugs_AL.pdf).

both federal<sup>171</sup> and state authorities<sup>172</sup> have moved against pharmacies and leading intermediaries involved in reimportation of drugs from Canada and, with rare exception,<sup>173</sup> have been successful in obtaining preliminary injunctions.<sup>174</sup>

The most extraordinary development in the reimportation scenario has been the interest of some state and municipal governments in reducing their drug costs by obtaining drugs from Canada. The issue was presaged by an exchange between the FDA and the State of California; concerned about the growing cost to its own pension fund, the State of California inquired about buying reimported drugs, but was rebuffed by the FDA.<sup>175</sup> Nonetheless, Montgomery, Alabama and Springfield,

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171. See, e.g., Press Release, Food & Drug Admin., FDA Takes Action Against Companies That Are Importing Unapproved, Potentially Unsafe Drugs (Sept. 9, 2003), <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00939.html>.

172. *Al. State Bd. of Pharm. v. Canadian Discount Drugs*, No. CV03287M (Ala. Dale County Ct. June 30, 2003) (granting temporary restraining order), [http://www.nacds.org/user-assets/PDF\\_files/AL\\_TRO\\_Canadian\\_Discount\\_Drugs.pdf](http://www.nacds.org/user-assets/PDF_files/AL_TRO_Canadian_Discount_Drugs.pdf); Plaintiff's Complaint, *Okla. State. Bd. of Pharmacy v. Rx Depot*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003) (No. 2003-2643), [http://www.nacds.org/user-assets/PDF\\_files/Oklahoma\\_BOP\\_Complaint.pdf](http://www.nacds.org/user-assets/PDF_files/Oklahoma_BOP_Complaint.pdf); Jean P. Fisher, *Board Sues Canadian Medicine Connections*, NEWS & OBSERVER, Oct. 17, 2003, <http://newsobserver.com/business/story/2953672p-2709936c.html>; see also Letter from Charles S. Campbell, Executive Director, Arkansas State Board of Pharmacy to Henry Jones, Rx Depot, [http://www.nacds.org/user-assets/PDF\\_files/AR\\_BOP\\_Letter\\_March\\_03.pdf](http://www.nacds.org/user-assets/PDF_files/AR_BOP_Letter_March_03.pdf) (Mar. 21, 2003); Letter from Rebecca H. Deschamps, Executive Director, Montana Board of Pharmacy to Gary Moffitt, Club Medzrx, [http://www.nacds.org/user-assets/PDF\\_files/Club\\_Medz\\_Cease\\_Desist\\_MT.pdf](http://www.nacds.org/user-assets/PDF_files/Club_Medz_Cease_Desist_MT.pdf) (Mar. 10, 2003).

173. The exception was a West Virginia circuit court that ruled against a state pharmacy board in favor of an intermediary on the basis that there was no evidence to show that anyone had been misled into confusing the intermediary with a pharmacy. Susan Bush, *W. Va. Court Decision Approves Importing of Drugs from Canada*, BERKSHIRE EAGLE, Jan. 2, 2004, <http://www.canadianpharmacytrust.com/media/news4.html>.

174. *United States v. Rx Depot, Inc.*, 290 F. Supp.2d 1238 (N.D. Okla. 2003); see also Julie Appleby, *Firms Told To Cease Canadian Drug Orders*, USA TODAY, Sept. 9, 2003, at 3B; Canadian Press, *U.S. Judge Agrees to Government Request To Shut Down Canadian Drug Importer* (Nov. 7, 2003), [http://mediresource.sympatico.ca/health\\_news\\_detail.asp?channel\\_id=10&menu\\_item\\_id=&news\\_id=2651](http://mediresource.sympatico.ca/health_news_detail.asp?channel_id=10&menu_item_id=&news_id=2651). But see *United States v. Rx Depot, Inc.*, 297 F. Supp. 2d 1306 (N.D. Okla. 2003) (motion for emergency stay denied).

175. Letter from William K. Hubbard, FDA Associate Commissioner for Policy and Planning, to Gregory Gonot, Deputy Attorney General, State of California, <http://www.fda.gov/opacom/gonot.pdf> (Aug. 24, 2003) (discussing Opinion No. 03-601).

Massachusetts have announced plans to supply their employees with drugs from Canada.<sup>176</sup> In response, the FDA targeted Springfield with a sting operation.<sup>177</sup> Iowa, Illinois, Vermont, and Minnesota have all requested a variance from federal law to set up importation programs.<sup>178</sup> New Hampshire has created a website that links to Canadian pharmacies from which prescription drugs can be ordered; the site requires original packaging and a prescription from a physician licensed in New Hampshire.<sup>179</sup> Minnesota has adopted a somewhat more cautious approach, setting up websites linking to Canadian pharmacies that meet its safety criteria.<sup>180</sup> Meanwhile, the Governor of Illinois<sup>181</sup> and the Massachusetts Attorney General<sup>182</sup> have publicly called for a liberalization of the FDA position. Throughout, the FDA has been resolute in its

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176. See Julie Appleby, *More Cities, States Opt for Canadian Drugs*, USA TODAY, Dec. 23, 2003, at 3B; Mathew Mosk, *Montgomery Explores Medicines from Canada*, WASH. POST, Nov. 2, 2003, at C7.

177. Christopher Rowland, *FDA Drug Scrutiny Rapped as Uneven*, BOSTON GLOBE, Nov. 16, 2003, at A1.

178. Tony Leys, *Vilsack Offers Plan on Canadian Drugs, Iowa Would Be Testing Ground for Purchase of Prescriptions*, DES MOINES REG., Jan. 22, 2004, at <http://desmoinesregister.com/news/stories/c4780934/23326025.html> (last visited May 1, 2004).

179. *Prescription Drugs for New Hampshire*, New Hampshire, at <http://www.nh.gov/governor/prescription/prescription.html> (last visited July 29, 2004); see also Anna Wilde Mathews, *States To Help Citizens Import Canadian Drugs*, WALL ST. J., Dec. 18, 2003, at B1.

180. *Welcome to Minnesota RxConnect Online*, Minnesota RxConnect Online, at <http://www.minnesotarxconnect.com> (last visited July 29, 2004); see Bruce Murphy, *State Plans Web Link to Canada Pharmacies*, MILWAUKEE J. SENTINEL, Dec. 23, 2003, at <http://www.jsonline.com/news/state/dec03/194984.asp>. Wisconsin planned a similar site but recanted; a message on the state website from Governor Doyle stated: "I would like to provide you with the names of those Web sites, but I can't. The Bush administration refuses to permit states to help people save money by purchasing medicine from Canada." Wisconsin Prescription Drug Resource Center, at <http://drugsavings.wi.gov> (last visited Feb. 8, 2004).

181. Press Release, Rod R. Blagojevich, *Blagojevich Calls on FDA To Reverse Policy on Importing Drugs from Canada* (Sept. 19, 2003), <http://www100.state.il.us/PressReleases/ShowPressRelease.cfm?SubjectID=1&RecNum=2283>; see also Monice Davey, *Illinois To Seek Exemption To Buy Drugs from Canada*, N.Y. TIMES, Dec. 22, 2003, at A27.

182. Christopher Rowland, *AG Pushes for Medicine from Canada*, BOSTON GLOBE, Oct. 14, 2003, at A1.

opposition,<sup>183</sup> has ramped up inspections on imported packages,<sup>184</sup> and has issued statements highly critical of some state actions.<sup>185</sup>

Congress has reacted somewhat negatively to the efforts to block drugs from Canada, viewing safety issues as exaggerated<sup>186</sup> and the FDA as siding with the pharmaceutical industry.<sup>187</sup> Ironically, legislation to permit reimportation already existed. The Medicine Equity and Drug Safety Act of 2000 (MEDS Act) was signed into law by President Clinton on October 28, 2000. The MEDS Act granted U.S. patients broad access to reimported drugs. Its implementation, however, was conditioned on the Department of Health and Human Services (HHS) completing a study and implementing regulations. Secretary Shalala<sup>188</sup> and Secretary Thompson, after the 2000 election, refused to implement the MEDS Act.<sup>189</sup> Secretary Shalala presciently identified practical flaws in the legislation that would have allowed pharmaceutical interests to nullify its intended effects.<sup>190</sup> Secretary Thompson, however, voiced concern about moving the United States from a “closed” distribution system, arguing that “opening our borders as required under this program would increase the likelihood that the shelves of pharmacies in towns and communities across the nation would include counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under

183. William M. Welch, *FDA on Canada Drugs: ‘No way’*, USA TODAY, Dec. 23, 2003, at 1A (quoting FDA Associate Commissioner Peter Pitts as saying “It’s very clear it’s absolutely illegal. . . . There’s no way importing drugs not FDA-approved can be legal in any way or form”).

184. Gardiner Harris & Monica Davey, *U.S. Steps Up Effort Against Drug Imports*, N.Y. TIMES, Jan. 24, 2004, at C1.

185. *Minnesota’s Canadian Drug Site Draws FDA Warning*, USA TODAY, Feb. 24, 2004, at [http://usatoday.com/tech/webguide/internetlife/2004-02-24-fda-minn-warning\\_x.htm](http://usatoday.com/tech/webguide/internetlife/2004-02-24-fda-minn-warning_x.htm) (reporting a letter sent by the FDA to Governor Pawlenty of Minnesota that noted “you . . . shine a bright light on a path used not only by profiteers masquerading as pharmacists, but by outright criminals”).

186. See, e.g., *U.S. House Members Slam FDA for Blocking Imports from Canada*, REUTERS HEALTH, Apr. 3, 2003.

187. *International Prescription Drug Parity, Hearing Before the House Gov’t Reform Subcomm. on Human Rights and Wellness*, 108th Cong. 1-5 (2003); see also Rowland, *supra* note 177.

188. Robert Pear, *In a Turnaround, White House Kills Drug-Import Plan*, N.Y. TIMES, Dec. 27, 2000, at A1.

189. Tommy G. Thompson, Secretary, Department of Health and Human Services, Response to Senator James Jeffords (July 9, 2001), <http://www.fda.gov/oc/po/thompson/medsact.html>.

190. Pear, *supra* note 188.

inappropriate and unsafe conditions.”<sup>191</sup>

Reimportation became a cause célèbre in the 108<sup>th</sup> Congress.<sup>192</sup> Several bills were introduced that prohibited discrimination against parallel importers by pharmaceutical companies,<sup>193</sup> essentially legalizing the Canadian connection.<sup>194</sup> Bi-partisan support in the House finally coalesced behind the Pharmaceutical Market Access Act of 2003.<sup>195</sup> This would have required the FDA to design and implement a system to grant individuals, pharmacists, and wholesalers in the United States access to FDA-approved drugs from FDA-approved facilities in industrialized nations including the European Union, Australia, and Canada, but not Mexico.<sup>196</sup> Senate and White House opposition, however, was strong,<sup>197</sup> and House action was more a warning shot to the administration regarding ongoing negotiations on prescription drug benefits and drug prices than a genuine commitment to legalizing reimportation. As the Medicare bill negotiations dragged on into the fall of 2003, there were signs that a robust reimportation provision was unlikely.<sup>198</sup> Nevertheless, as the AARP noted when it endorsed the bill,

191. Thompson, *supra* note 189.

192. *See, e.g.*, Preserving Prescription Drugs Discounts Act, S. 477, 108th Cong. (2003); North American Prescription Price Equity Act of 2003, H.R. 354, 108th Cong. (2003); Prescription Drug Affordability Act, H.R. 616, 108th Cong. (2003); Senior Bill of Rights Act of 2003, H.R. 1733 108th Cong. (2003); Preserving Access to Safe, Affordable Canadian Medicines Act of 2003, H.R. 847, 108th Cong. (2003); Medical Independence, Privacy, and Innovation Act of 2003, H.R. 2196, 108th Cong. (2003); Prescription Drug Benefit and Cost Containment Act of 2003, S. 7, 108th Cong. (2003); *see also* Prescription Drug Price Reduction Act, H.R. 5534, 107th Cong. (2002); Drug Importation Act of 2002, H.R. 5186, 107th Cong. (2002); Personal Prescription Drug Import Fairness Act, H.R. 1229, 107th Cong. (2002); Affordable Drugs Access Act, H.R. 5217, 107th Cong. (2002); H.R. 4614, 107th Cong. (2002); Prescription Drug Price Parity for Americans Act, H.R. 2244, 107th Cong. (2002); Prescription Drug Affordability Act, H.R. 2801, 107th Cong. (2002); Prescription Reimportation, Improvement, Correction, and Enhancement Act, H.R. 698, 107th Cong. (2002).

193. *E.g.*, Preserving Access to Safe, Affordable Canadian Medicines Act, H.R. 847, 108th Cong. (2003).

194. *E.g.*, Prescription Drug Parity for Americans Act, H.R. 2497, 108th Cong. (2003).

195. H.R. 2427, 108th Cong. (2002); *see also* Robert Novak, *Drug Company Backlash Hits Fever Pitch in Congress*, CHI. SUN-TIMES, July 17, 2003, at 33.

196. *See* Jim VandeHei & Juliet Eilperin, *House Approves Drug Reimports*, WASH. POST, July 26, 2003, at A1.

197. Nick Anderson, *In Senate, Stiff Resistance to a Drug-Import Bill*, LA TIMES, July 26, 2003, at 1-10.

198. *See* Amy Goldstein & Helen Dewar, *Hill Negotiators Rethink Reimported Drugs*, WASH. POST, Nov. 6, 2003, at A2.

“It is a national embarrassment that in a country with the most advanced medical system in the world, so many of our citizens can obtain affordable prescription drugs only by seeking them in foreign countries.”<sup>199</sup> Legalized reimportation was dropped from the final Medicare legislation, replaced by what is in essence an update of the MEDS Act.<sup>200</sup> However, Congress continues to consider legislation seeking to liberalize reimportation of prescription drugs.<sup>201</sup>

#### IV. UNDERSTANDING THE STAKEHOLDERS

In 1999, President Clinton initiated the current war on Internet drug sales, signaling “zero tolerance for prescription drug Internet sites that ignore federal and state laws and harm patient safety and health.”<sup>202</sup> In fact, there is even more at stake. Simmering behind the layers of regulation, parochial regulators, and patchy enforcement are crucial questions about the future of U.S. healthcare delivery. Most aspects of e-health, Internet prescribing and dispensing in particular, are disruptive technologies that challenge the status quo.<sup>203</sup> The stakeholders have frequently divergent views on the specific issues and the role of technologically mediated care.

##### *A. Federal and State Regulators*

It should be clear from the discussion above that U.S. drug marketing, prescribing, and fulfillment exists in an immensely complex regulatory matrix involving state, federal, and professional bodies. The matrix affects more than local professional regulations and national quality regulation,

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199. Dan Balz, *Edwards Seeks a Lift with TV Ads*, WASH. POST, Aug. 7, 2003, at A3 (discussing a letter from AARP to sponsoring House members Reps. Emanuel and Gutknecht).

200. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2469 (replacing 21 U.S.C. § 384). The 2003 legislation calls for a study of reimportation similar to that called for by the MEDS Act. FDA Commissioner (and CMS Secretary designate) Mark McClellan has been appointed to head the study. *McClellan To Study Drug Imports*, WALL ST. J., Feb. 26, 2004, at D4.

201. See, e.g., Pharmaceutical Market Access and Drug Safety Act of 2004, S. 2328, 108th Cong. (2004).

202. PBS, *Clinton Proposes Regulation of Internet Drug Sales*, Public Broadcasting Service, at [http://www.pbs.org/newshour/updates/december99/internet\\_drugs\\_12-28.html](http://www.pbs.org/newshour/updates/december99/internet_drugs_12-28.html) (Dec. 28, 1999).

203. See generally PHILIP EVANS & THOMAS S. WURSTER, BLOWN TO BITS: HOW THE NEW ECONOMICS OF INFORMATION TRANSFORMS STRATEGY 180-89 (2000).

but also strong criminal enforcement (e.g., DEA) necessitated by the distribution of illegal controlled substances and the diversion of legally prescribed drugs.<sup>204</sup> The international connection adds more complexity as stakeholders confront not only illegal and offshore<sup>205</sup> sources but also the more benign, yet politically charged, Canadian connection.

The shifts in healthcare delivery implicate even broader interests for regulators in the United States. Some of these interests are consistent with a more positive approach to technologically-mediated care, while others are the product of conservatism, parochialism, protectionism, and even technophobia.

The federal government is committed to leveraging health technology to decrease costs and improve medical quality.<sup>206</sup> The Bush Administration has tried to assuage industry concerns about the HIPAA privacy regulations but has remained committed to the introduction of the foundational health Electronic Data Interchange (EDI) system.<sup>207</sup> The federal government remains committed to inter-operability and technology-led efficiency in interstate medical and insurance markets.<sup>208</sup> Federal regulators recognize that the cost-savings of technologically-mediated care will be

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204. One example is the abuse of OxyContin. See *OxyContin Diversion and Abuse*, U.S. D.O.J. INFORMATION BULLETIN, Jan. 2001, at 1, available at <http://www.usdoj.gov/ndic/pubs/651/651p.pdf>.

205. See Melissa K. Cantrell, *The Taming Of E-Health: Asserting U.S. Jurisdiction over Foreign and Domestic Websites*, 103 W. VA. L. REV. 573 (2001); Ivette P. Gomez, Note, *Beyond the Neighborhood Drugstore: U.S. Regulation of Online Prescription Drug Sales by Foreign Businesses*, 28 RUTGERS COMPUTER & TECH. L.J. 431 (2000).

206. See, e.g., Press Release, United States Department of Health & Human Services, Secretary Thompson Announces Steps To Reduce Medication Errors (Mar. 13, 2003), <http://www.hhs.gov/news/press/2003pres/20030313.html>; Ceci Connolly, *Bar Codes on Drugs Proposed, Errors Could Be Cut by Matching Hospital Patient, Prescription*, WASH. POST, Mar. 8, 2003, at A7.

207. HIPAA's "Administrative Simplification" Subtitle F, sets out the framework and provided CMS with the regulatory authority "to improve . . . the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 261, 110 Stat. 2021 (1996). The pivotal "Administrative Simplification" subtitle introduced by the HIPAA regulations was the establishment of an Electronic Data Interchange (EDI) for the healthcare system. When fully implemented, this EDI architecture will provide for a fully interoperable, standardized system for processing all data exchanges between healthcare entities.

208. This commitment is evidenced by the introduction of the administrative simplification system. See *infra* note 207.



realized more rapidly if consumers have confidence in the new systems, which requires that providers internalize many of the privacy and security costs in the healthcare information domain.

The White House has subordinated concerns about medical error to the more populist rhetoric of the “malpractice crisis,”<sup>209</sup> although in the 2004 State of the Union address the expected populist oversimplification of “we must eliminate wasteful and frivolous medical lawsuits” was followed by a more technical and forward-thinking directive— “[b]y computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care.”<sup>210</sup> Federal agencies continue to push initiatives, such as e-prescribing,<sup>211</sup> that directly reduce error<sup>212</sup> or indirectly decrease patient information costs in choosing safe providers through increased reporting, analysis and disclosure.<sup>213</sup>

Other federal goals are less clearly stated. Federal regulators appear desperate to cut health costs by encouraging states to use technology to increase the efficiency of federally-funded intrastate services and are thus re-thinking reimbursement and subsidy programs. Although there are articulated federal goals to prevent distortions in market conditions between states,<sup>214</sup> these have not been applied in the e-health domain. Finally, the principle of comity<sup>215</sup> suggests a conservative approach to dealing with international traffic in drugs; the United States needs to

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209. “Because of excessive litigation, everybody pays more for healthcare, and many parts of America are losing fine doctors. No one has ever been healed by a frivolous lawsuit; I urge the Congress to pass medical liability reform.” George W. Bush, State of the Union Address, <http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html> (Jan. 28, 2003); see also Jeanne Cummings, *Doctors’ Activism Revives Malpractice Bill; Inspired By Bush, Physicians Are Pressuring Congress To Cap Damage Awards*, WALL ST. J., Jan. 13, 2003, at A4.

210. George W. Bush, State of the Union Address, <http://www.whitehouse.gov/news/releases/2004/01/20040120-7.html> (Jan. 20, 2004).

211. See *supra* note 17.

212. One example is the work of the Agency for Healthcare Research and Quality (AHRQ).

213. See *infra* notes 475-477.

214. Cf. *infra* text accompanying note 311 (discussing FTC report on the interstate wine market).

215. “Comity, in the legal sense, is neither a matter of absolute obligation, on the one hand, nor of mere courtesy and good will, upon the other. But it is the recognition which one nation allows within its territory to the legislative, executive, or judicial acts of another nation, having due regard both to international duty and convenience, and to the rights of its own citizens, or of other persons who are under the protection of its laws.” *Hilton v. Guyot*, 159 U.S. 113, 163-64 (1895).

respect borders in order to gain international cooperation in curtailing illegal traffic in a wide array of Internet enabled goods and services, whether child pornography, gambling, or pharmaceuticals.

Today, improvements in health quality and safety primarily flow from federal initiatives (e.g., the FDA and the Agency for Healthcare Research and Quality), Medicare/Medicaid standards, and other national initiatives such as those emanating from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Leapfrog Group,<sup>216</sup> and the Markle Foundation's "Connecting for Health Collaborative."<sup>217</sup> The blunter instruments of state-law discipline and malpractice litigation have been overshadowed by these initiatives.

State health departments have specific positive experiences with technologically mediated care, such as telemedical outreach to underserved populations,<sup>218</sup> and increasingly leverage technology to provide a greater range of intrastate services.<sup>219</sup> State regulators, however, have failed to articulate any discrete local quality standards and safety interests in an increasingly national healthcare delivery system. State medical boards continue to give credence to the fallacy that quality and safety can be addressed by rooting out the few "bad apples" in the professions, while appearing to be less than conversant with national process or system-wide problems of medication errors, wrong-site surgery, iatrogenic injury, physician fatigue, and the nursing shortage.<sup>220</sup> Furthermore, rather than taking a holistic approach to quality of care, state boards tend to concentrate on discrete, often interpersonal violations of their codes (e.g., sexual relations with patients, substance abuse and, of course, Internet prescribing).

In the areas of licensure and discipline, the states continue to take their police powers very seriously. Yet, they reference only the broadest notions of quality and the protection of the public health. Despite the flurry of enforcement activity surrounding Internet prescribing and dispensing, state medical boards are principally interested in interactions

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216. The Leapfrog Group, at <http://www.leapfroggroup.org> (last visited Apr. 17, 2004).

217. Connecting for Health, at <http://www.connectingforhealth.org> (last visited Apr. 17, 2004).

218. See, e.g., *Telemedicine Reaches over 200 Alaska Locations*, ALASKA J. COMM., Jan. 27, 2003.

219. See, e.g., Virginia Board of Medicine's Practitioner Information Website, at <http://www.vahealthprovider.com/> (last visited Apr. 17, 2004).

220. See generally Lucian L. Leape, *Preventing Medical Accidents: Is "Systems Analysis" the Answer?*, 27 AM. J.L. & MED. 145, 147 (2001) (arguing human errors can be "prevented by redesigning systems . . . to make it difficult to impossible for the errors to occur"); James Reason, *Human Error: Models and Management*, 320 BRIT. MED. J. 768 (2000).

within their own borders. In some interstate interactions, they do, however, rightfully assert their right to make policy. For example, medical boards have to counter negative externalities suffered by their citizens when neighbor states fail to enforce their licensure rules regarding “exported” prescribing and dispensing services.<sup>221</sup>

Both state and federal regulators view Internet prescribing and dispensing negatively and have derived moral imperatives from its more dangerous and obviously illegal practices. Regulators have targeted telemedicine in order to better police cybermedicine and Internet prescribing. Similarly, they target prescribing and dispensing because of tangential goals, such as consumer protection and public health. As a result, regulatory activity tied to Internet prescribing and dispensing is frequently prophylactic—leveraging the “hard” law of licensure to curtail conduct that offends other policies or laws—yet it is more difficult to regulate using “softer” consumer protection laws or offences requiring a showing of *mens rea*.

Legally suspect cyber-physicians and e-pharmacies indulge in the same array of dubious practices as their gambling and pornography fellow travelers: auction fraud, credit card fraud, and non-delivery of merchandise.<sup>222</sup> Grey and black-market sites are not interested in “stickiness” or persistence,<sup>223</sup> or otherwise creating a marketing and service atmosphere that promotes repeat business. These operators subscribe to a more practical and immediate imperative: to keep moving and morphing to stay ahead of pursuing regulators. Bad service, poor quality products, and even outright fraud are therefore par for the course.<sup>224</sup>

The Federal Trade Commission (FTC) and state consumer protection agencies are active in the prescribing and fulfillment domains,<sup>225</sup> but their

221. This is what Goldsmith and Sykes would call a “nonpecuniary externality that affects citizens outside of the regulating state.” Jack L. Goldsmith & Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 YALE L.J. 785, 798 (2001).

222. NAT’L WHITE COLLAR CRIME CTR. & FED. BUREAU OF INVESTIGATION, IFCC 2002 INTERNET FRAUD REPORT, JANUARY 1, 2002—DECEMBER 31, 2002, at 5 (2003), available at [http://www1.ifccfbi.gov/strategy/2002\\_IFCCReport.pdf](http://www1.ifccfbi.gov/strategy/2002_IFCCReport.pdf) (last visited Apr. 16, 2004).

223. For an explanation of this concept, see Martin Nemzow, Array Development Ecommerce “Stickiness” for Customer Retention, at <http://www.arraydev.com/commerce/jibc/9908-03.htm> (last visited Apr. 16, 2004).

224. See Internet Prescribing, Medical Board of California, at <http://www.medbd.ca.gov/buyerbeaware.htm> (last visited Apr. 16, 2004) (explaining the risks associated with ordering prescriptions through the internet).

225. See, e.g., *The Internet Sale of Prescription Drugs from Domestic Websites: Hearings Before the House Comm. on Gov’t Reform*, 108th Cong. (2003) (prepared statement of J. Howard Beales,

regulatory powers are somewhat limited, often generalized, and frequently limited to cases where misrepresentation or fraud can be proved.<sup>226</sup> The FTC has argued that "the Commission has authority to bring an enforcement action where an online pharmacy makes false or misleading claims about the products or services it provides. However, the online prescribing and dispensing of prescription drugs that does not involve a deceptive or unfair practice generally does not fall within the agency's scope of authority."<sup>227</sup>

Regulatory interests are also sparked by concerns over pricing. The Canadian connection that opens a channel to less expensive drugs is the exception that proves the rule. Unlike the majority of goods and services offered over the Web, Internet prescribing and dispensing do not attract consumers primarily because of lower prices. In fact, many are seeking drugs that their own physicians refuse to prescribe and are prepared to pay a premium for back-channel services. Paul Starr recounts how in the late 1890s a patent medicine company pandered to Victorian modesty, attracting women customers away from male physicians with advertisements such as "Do you want a strange man to hear all about your particular diseases?" and "Men NEVER See Your Letters."<sup>228</sup> For many lifestyle drugs, stealth and anonymity may still be the predominant factors promoting online purchases.<sup>229</sup>

The Internet's oft-touted transactional transparency (based on reduced transaction costs and generally low information costs)<sup>230</sup> does not seem to apply to the current traffic in interstate prescription drugs. A survey by the California State Board of Pharmacy even concluded that some drugs cost five times as much on the Internet as they did in local

III, Director, Bureau of Consumer Protection of the Federal Trade Commission), [hereinafter *Hearings*], <http://www.ftc.gov/os/2003/03/030327internetprescriptions.pdf> (last visited Apr. 16, 2004).

226. See, e.g., Press Release, Fed. Trade Comm'n, Online Pharmacies Settle FTC Charges (July 12, 2000), <http://www.ftc.gov/opa/2000/07/iog.htm>; see also Press Release, Fed. Trade Comm'n, FTC Charges Direct Marketers of Ephedra Weight Loss Products with Making Deceptive Efficacy and Safety Claims (July 1, 2003), <http://www.ftc.gov/opa/2003/07/ephedra.htm>.

227. *Hearings*, *supra* note 225, at 11 (footnotes omitted).

228. PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 128 (1982).

229. For the views on patient motives from a doctor who has written more than 10,000 Internet prescriptions for Viagra, see Miles J. Jones & William Alvis Thomasson, *Establishing Guidelines for Internet-based Prescribing*, 96 S. MED. J. 1, 2-3 (2003).

230. For a thoughtful analysis, see Robert P. Merges, *The End of Friction? Property Rights and Contract in the "Newtonian" World of On-Line Commerce*, 12 BERKELEY TECH. L.J. 115 (1997).

pharmacies.<sup>231</sup>

This counter-intuitive phenomenon was at the root of the prosecutors' failed attempt in *State ex rel. Stovall v. Confimed.com, L.L.C.*<sup>232</sup> to persuade the Supreme Court of Kansas that a charge of seventy-five dollars for an online consultation and dispensing fee was unconscionable.<sup>233</sup> However, infomediaries such as price "bots" (websites that offer price comparisons across multiple suppliers) are moving into the prescription drug domain, providing comparison pricing information across online and bricks-and-mortar suppliers.<sup>234</sup>

Federal authorities have been extensively involved in attempts to crack down on abuses such as fraud and diversion. For example, "Operation Web Slinger," a joint U.S.-Canadian investigation coordinated by the DEA, has targeted the illegal Internet trafficking of "date rape" drugs such as GHB.<sup>235</sup> Similarly, the FTC and FDA are jointly leading "Operation Cure.All,"<sup>236</sup> directing considerable federal law enforcement energies against companies marketing fraudulent health products over the Internet. Targeted companies include those that market nutritional supplements, herbal products, and medical devices that claim to treat ailments as diverse as cancer, HIV/AIDS, arthritis, hepatitis, Alzheimer's disease, and diabetes.<sup>237</sup> A particularly disturbing set of cases arose after September 11, 2001 with online entrepreneurs offering "civil defense" products such as

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231. Siwolop, *supra* note 88. A PharmacyChecker.com analysis reported that U.S. sites not requiring prescriptions charged, on average, fifty-four percent more than sites that do require prescriptions. PharmacyChecker.Com, *Fifty Percent of Internet Pharmacies Not Licensed According to Pharmacychecker.Com; Canadian Prices Half That of U.S.*, Pharmacy Checker, at [http://www.pharmacychecker.com/news/news\\_040703.asp](http://www.pharmacychecker.com/news/news_040703.asp) (Apr. 7, 2003).

232. 38 P.3d 707 (Kan. 2002). For a full discussion of *Stovall*, see *infra* note 411 and accompanying text.

233. 38 P.3d at 714 ("[The investigators] at best made a bad bargain, but, lacking any indication of deceptive bargaining conduct or unequal bargaining power, the \$ 75 charge for the consultation was not unconscionable.").

234. For an example of such a company, see DestinationRx, at <http://www.destinationrx.com> (last visited Apr. 16, 2004).

235. Press Release, Drug Enforcement Admin., "Date Rape" Drug Sold over the Internet (Sept. 19, 2002), <http://www.usdoj.gov/dea/pubs/pressrel/pr091902.html>.

236. Greg Winter, *U.S. Vows More Scrutiny of Health Ads on Net*, N.Y. TIMES, June 15, 2001, at C4; see Press Release, Fed. Trade Comm'n, "Operation Cure.All" Wages New Battle in Ongoing War Against Internet Health Fraud (June 14, 2001), at <http://www.ftc.gov/opa/2001/06/cureall.htm>.

237. See, e.g., *Herb Remedy Web Sites Break Law, Study Finds*, AKRON BEACON J., Oct. 28, 2003.

anti-radiation pills<sup>238</sup> or Ciprofloxacin, designed to treat Anthrax.<sup>239</sup> Such cases replicated themselves after other public health scares such as the SARS outbreak.<sup>240</sup> State and federal authorities will likely continue to target the Internet sale of other dangerous products such as nicotine-laced lollipops,<sup>241</sup> or those likely to be used for illegal purposes such as “cleaning” urine.<sup>242</sup> Regulators in the United States face a growing problem of counterfeit<sup>243</sup> and contaminated drugs,<sup>244</sup> and are particularly keen to slow the development of new or suspect distribution channels.<sup>245</sup>

### *B. The Pharmaceutical Industry*

It is relatively easy to paint the U.S. pharmaceutical industry as the real villain in the Internet dispensing controversy. After all, the industry is stimulating demand for pharmaceuticals by marketing to physicians<sup>246</sup> and through DTC advertising,<sup>247</sup> and the industry also must appreciate that the drugs for which they create this demand are frequently out-of-formulary<sup>248</sup>

238. *New York Says Pill Seller Invoked Terror Case*, N.Y. TIMES, Dec. 4, 2002, at A19.

239. See Press Release, Fed. Trade Comm’n, FTC Cracks Down on Marketers of Bogus Bioterrorism Defense Products (Nov. 19, 2001), <http://www.ftc.gov/opa/2001/11/webwarn.htm>.

240. *Internet Is Awash in Ads for Products Promising Cures or Protection*, N.Y. TIMES, Apr. 14, 2003, at A12.

241. See, e.g., Press Release, Fed. Trade Comm’n, FDA Warns Sellers of Nicotine Lollipops & Lip Balm That Their Products Are Illegal (Apr. 10, 2002), <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01144.html>.

242. See, e.g., *Curtis v. State*, 549 S.E.2d 591 (S.C. 2001).

243. See, e.g., Lauren Neergaard, *FDA Says Web Site Is Selling Counterfeit Contraceptives*, WASH. POST, Feb. 4, 2004; see also FOOD & DRUG ADMIN., COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION (2004), [http://www.fda.gov/oc/initiatives/counterfeit/report02\\_04.html](http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html).

244. See, e.g., *Lax System Allows Criminals To Invade the Supply Chain*, WASH. POST, Oct. 22, 2003, at A01; *U.S. Prescription Drug System Under Attack*, WASH. POST, Oct. 19, 2003, at A01.

245. See FOOD & DRUG ADMIN., *supra* note 150.

246. Robert Pear, *U.S. Warns Drug Makers on Illegal Sales Practices*, N.Y. TIMES, Apr. 28, 2003, at A16; cf. Press Release, PhRMA, PhRMA Adopts New Marketing Code (Apr. 19, 2002), <http://www.phrma.org/mediaroom/press/releases/19.04.2002.390.cfm>.

247. See, e.g., Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141 (1997); David W. Opderbeck, *How Should FDA Regulate Prescription Drug Promotion on the Internet?*, 53 FOOD DRUG L.J. 47 (1998); Peter S. Reichertz, *Understanding Government Regulation of the Marketing and Advertising of Medical Devices, Drugs, and Biologics: The Challenges of the Internet*, 52 FOOD DRUG L.J. 303 (1997).

248. In 2002, out-of-pocket spending on prescription drugs increased from \$6.1 billion

and potentially off-label, and so are less likely to be satisfied through traditional prescribing or dispensing channels.<sup>249</sup>

It also seems beyond cavil that U.S. pharmaceutical companies regularly practice price and distribution discrimination, with the U.S. market bearing disproportionate and escalating drugs costs. The primary reason for the lower costs abroad, however, is that non-U.S. healthcare delivery services are larger, monopsonic, or have otherwise put themselves into better bargaining positions with pharmaceutical companies. In particular, non-U.S. national health services are willing to use their monopoly purchasing power to extract low prices for pharmaceuticals. Arguably, the real objection to the high costs of pharmaceuticals in the United States is that the pharmaceutical companies, forced to internalize costs in foreign markets, disproportionately externalize their research and development costs to U.S. consumers. The federal government has done little to reverse this trend and the states have only recently begun to explore their market power by forming procurement collectives.<sup>250</sup> Illustrative of the U.S. drug pricing dynamic has been the pharmaceutical industry's opposition to a Medicare prescription drug benefit, which is driven by the fear that centralized government purchasing would drive

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to \$48.6 billion, or twenty-three percent of out-of-pocket spending. Robert Pear, *Health Spending Rises to Record 15 % of Economy*, N.Y. TIMES, Jan. 9, 2004. According to the GAO,

Pharmaceutical companies have increased spending on DTC advertising more rapidly than they have increased spending on research and development. Between 1997 and 2001, DTC advertising spending increased 145 percent, while research and development spending increased 59 percent. Promotion to physicians accounted for more than 80 percent of all promotional spending by pharmaceutical companies in 2001. Total promotional spending was equivalent to 12 percent of drug sales in the United States in 2001.

GEN. ACCOUNTING OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 3 (GAO-03-17, 2002) [hereinafter PRESCRIPTION DRUGS].

249. "Ninety percent of the people who buy medications at PlanetRx pay for the prescriptions themselves, not through their insurance plans, whereas only 20 percent of the customers at brick-and-mortar pharmacies pay out of their own pocket." Jennifer Couzin, *The Internet's Drug Lords*, THE INDUSTRY STANDARD, Apr. 10, 2000. The GAO has also noted:

To date, the few studies that have examined the effects of DTC spending on prescription drug spending and utilization have found that DTC advertising increases both. In addition, there is clear evidence from consumer surveys that DTC advertising encourages consumers to request prescriptions for specific brand-name drugs from their physicians and that some physicians provide the requested prescription.

PRESCRIPTION DRUGS, *supra* note 248, at 11.

250. Milt Freudenheim, *Nine States Form Group To Lower Drug Costs*, S.D. UNION-TRIB., Jan. 14, 2003, at A1.

down prices<sup>251</sup> or that cost-effectiveness analysis would counter pharmaceutical marketing and create limited formularies.<sup>252</sup>

### *C. Physicians and Pharmacists*

Although patients are apparently keen to increase the level of technological intermediation with their healthcare providers,<sup>253</sup> it can be difficult to find reciprocal interest among physicians<sup>254</sup> or institutional providers.<sup>255</sup> Despite evidence that use of rich and self-documenting email,<sup>256</sup> as well as other robust electronic communications with patients,<sup>257</sup> make treatment more effective, many physicians and their representatives on state boards view email and web contact with patients or potential patients as further signs (along with managed care, Internet web advice, and the general "HIPAA-ization" of medical practice)<sup>258</sup> that they are losing control of the physician-patient relationship.<sup>259</sup>

251. Jim Drinkard, *Drug Bill a Well-Financed Victory for Industry; Companies Avert Version Feared Most*, USA TODAY, July 7, 2003, at 4A.

252. Robert Pear, *Congress Weighs Drug Comparisons*, N.Y. TIMES, Aug. 24, 2003, at 18.

253. See *infra* notes 275-279.

254. According to one study, seventy-four percent of parents of children wish to communicate with their children's doctors online, but seventy-nine percent of pediatricians are unwilling to communicate directly with patients via email. Katie D. Kleiner et al., *Parent and Physician Attitudes Regarding Electronic Communication in Pediatric Practices*, 109 PEDIATRICS 740 (2002).

255. Beth Healy, *Health Plans Fall Short in Web Service, Study Finds*, BOSTON GLOBE, Apr. 9, 2003, at D1 ("The more consumers access information about their health in general online, and the more premiums and copays that are pushed onto their shoulders, the more they want to be treated like customers." ) (quoting Forrester Research study)).

256. Leonard Holmes, *Writing Email About Problems Can Improve Health*, About.com., at <http://mentalhealth.about.com/library/sci/0402/blemail402.htm> (last visited Apr. 16, 2004); see also Florian Strasser et al., *E-motions: Email for Written Emotional Expression*, 20 J. CLINICAL ONCOLOGY 3352 (2002).

257. See, e.g., *Virtual Visits' Helping Parents of Premies*, N.Y. TIMES, Dec. 5, 2000, at 14 (reporting that premature infants whose families had web access to updates on the babies' health, information about medical conditions, explanations of medical equipment and terminology, and a videoconferencing system with which to interact with medical staff had shorter stays in neonatal intensive care units).

258. See *supra* note 56 and accompanying text.

259. See Edd Fleming & Jens Riese, *On-line Healthcare: Why Are Physicians Still Dragging Their Feet?*, HEALTHLEADERS, at [http://www.healthleaders.com/news/feature1.php?contentid=11288&CE\\_Session=47b808616122e9a96290e0574f68fb83](http://www.healthleaders.com/news/feature1.php?contentid=11288&CE_Session=47b808616122e9a96290e0574f68fb83) (Feb. 5, 2001).



Less frequently articulated are genuine concerns about the legal and operational uncertainties surrounding patient email.<sup>260</sup> Although some guidance for professionals has been published,<sup>261</sup> genuine questions remain about legal exposure for responding to unsolicited email,<sup>262</sup> and the related question of exactly what creates a physician-patient relationship on the Internet.<sup>263</sup> Such uncertainties include: difficulties in positively identifying online participants; questions about responsibility for “operator error” or mistakenly forwarded e-mail; the chilling effect of HIPAA’s security and privacy rules; and the scope of document retention,<sup>264</sup> particularly the way that the self-documenting nature of email may increase malpractice exposure.

Physicians also have understandable “business” concerns. They view email communications with patients as creating an expectation of around-the-clock services and something to be delegated to their staff.<sup>265</sup> This antipathy is, no doubt, fuelled by the relative lack of reimbursement for any such contact with patients.<sup>266</sup> In contrast, physicians involved in subscription-based email services show considerably more enthusiasm.<sup>267</sup>

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260. See Katie Hafner, *Dear Doctor Meets Return to Sender*, N.Y. TIMES, June 6, 2002, at G1; Francesca Lunzer Kritz, *Some Doctors Use Patient E-mail in Their Practices, but Most Aren’t Ready To Log on*, WASH. POST, Apr. 1, 2003, at HE1.

261. See, e.g., Beverly Kane & Daniel Z. Sands, *Guidelines for the Clinical Use of Electronic Mail with Patients*, 5 J. AM. MED. INFORMATICS ASS’N 104 (1998), [http://www.amia.org/pubs/other/email\\_guidelines.html](http://www.amia.org/pubs/other/email_guidelines.html).

262. See, e.g., MV Seeman & B Seeman, *E-psychiatry: The Patient-Psychiatrist Relationship in the Electronic Age*, 161 CANADIAN MED. ASS’N J. 1147 (1999) (“Clearly, the most judicious course of action is not to respond to email queries.”).

263. This is analogous to the telephone cases where “it must be shown that it was foreseeable that the prospective patient would rely on the advice and that the prospective patient did in fact rely on the advice.” *Miller v. Sullivan*, 625 N.Y.S.2d 102, 104 (App. Div. 1995). Chat functions, and in some instances email, are more likely to trigger this formal relationship due to the contemporaneous nature of relationship creation and provision of services.

264. NASD has a three-year rule for retention of email and IM communications. *Notice to Members*, at <http://www.nasdr.com/pdf-text/0333ntm.pdf> (last visited Apr. 17, 2004).

265. See Hafner, *supra* note 260. See generally CA. HEALTHCARE FOUND., *ONLINE PATIENT-PROVIDER COMMUNICATION TOOLS: AN OVERVIEW* 19-25 (2003), <http://www.chcf.org/documents/ihealth/PatientProviderCommunicationTools.pdf>.

266. See Laura Landro, *The Informed Patient: Please Get the Doctor Online Now*, WALL ST. J., May 22, 2003.

267. See, e.g., GreenField Health System, at <http://www.greenfieldhealth.com/>. See generally *E-Mail Could Transform Medical Care*, Northwest News Channel 8, at

As for pharmacists, David Brushwood has argued convincingly that the changing nature of medical practice and health policy leads to pharmacists “being asked to do more for each patient, and there are more patients whose needs pharmacists are being asked to meet.”<sup>268</sup> This trend will continue as medical practice continues to favor pharmaceutical treatment models while at the same time relying on the pharmacist as the second line of defense to reduce medication errors.

Just as it is naïve to paint pharmaceutical companies as the villains of this story, it would stretch credulity to classify most Internet physicians and pharmacists as victims. They may characterize themselves as guiltless pioneers protecting the access rights of their customers, but most of their businesses and business practices too closely resemble those employed by less reputable Internet sites. Internet physicians and pharmacies market through spam<sup>269</sup> and impede the continuity of care by disappearing and reappearing under different names and web addresses.<sup>270</sup> The shadow-writer or ghost-writer physicians they often employ must either possess superhuman powers or ignore quality of care given the hundreds of prescriptions they sign per week.<sup>271</sup>

By the same token, Internet physicians and pharmacists cannot be viewed as innocent victims of an overly complex regulatory system. Internet prescribers and dispensers are generally quite sophisticated and structure their businesses to exploit “soft” states or regulatory gaps. If they were willing, they could avoid controlled substances, develop track records of quality practices, decouple their prescribing and dispensing businesses,

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[http://www.kgw.com/health/stephanie\\_stricklen/stories/kgw\\_0423\\_health\\_stricklen\\_email\\_doctors.lca31ac9.html](http://www.kgw.com/health/stephanie_stricklen/stories/kgw_0423_health_stricklen_email_doctors.lca31ac9.html) (Apr. 23, 2002).

268. David B. Brushwood, *Responsive Regulation of Internet Pharmacy Practice*, 10 ANN. HEALTH L. 75, 76 (2001).

269. The spam subject line “Check out our new lower prices. Many ‘drug’ types available.” made SurfControl’s list of “Top 10 Most Annoying Spam in 2002.” Press Release, SurfControl, Anti-Spam Leader SurfControl Cites Top 10 Most Annoying Spam in 2002, at <http://www.surfcontrol.com/news/newsitem.aspx?id=543> (last visited Apr. 17, 2004). According to Clearswift, healthcare spam accounted for almost fifty percent of spam in November 2003. Press Release, Clearswift, Spammers Peddling Viagra and Diet Pills in Run Up to Party Season (Dec. 16, 2003), <http://www.clearswift.com/news/pressreleases/232.aspx>.

270. “It’s like rabbits,” said Wayne A. Michaels, a senior investigator for the Drug Enforcement Administration. “Every day, there are more of them. They’re up, they’re down, they’re foreign, they’re domestic.” Gilbert M. Gaul & Mary Pat Flaherty, *Internet Trafficking in Narcotics Has Surged*, WASH. POST, Oct. 20, 2003, at A01.

271. See Gaul & Flaherty, *supra* note 18.

and restrict their operations to one or a small number of states where their physicians are licensed—either by refusing to prescribe to patients in states where their doctors are not licensed or by using what Jack Goldsmith has called “information discrimination technology.”<sup>272</sup>

#### *D. Patients*

Patient interest in Internet prescribing and dispensing is not difficult to explain; it is part of a broader pattern of consumer use of health-related email and web resources.<sup>273</sup> Searching for health information and advice is one of the primary uses of the Internet in the United States, behind only email and product research.<sup>274</sup> Eighty percent of, or 110 million, online adults use the Internet to access health information.<sup>275</sup> Forty-five percent of U.S. adults use the Internet for healthcare-related purposes, including health research, prescribing, and comparison-shopping on health services.<sup>276</sup> Thirty-four percent of Internet users have searched for pharmaceutical-related information.<sup>277</sup> In contrast, only sixteen percent refer to their physicians for health-related information.<sup>278</sup>

Ninety percent of adults online would like to communicate online with

272. Jack L. Goldsmith, *Against Cyberanarchy*, 65 U. CHI. L. REV. 1199, 1225 (1998).

273. See FOX & FALLOWS, *supra* note 54.

274. *Id.* at i.

275. Humphrey Taylor, *Cyberchondriacs Update*, Harris Interactive, at [http://www.harrisinteractive.com/harris\\_poll/index.asp?PID=299](http://www.harrisinteractive.com/harris_poll/index.asp?PID=299) (May 1, 2002). This is compared to fifty-four million in 1998, sixty-nine million in 1999, and ninety-seven million in 2001. *Id.*

276. Press Release, Solucient, Nearly Half of U.S. Adults Turn to Web for Health Care Needs (July 15, 2003), [http://www.solucient.com/news\\_press/news20030715.shtml](http://www.solucient.com/news_press/news20030715.shtml) (last visited Apr. 17, 2004).

277. See FOX & FALLOWS, *supra* note 54, at 8.

278. *Id.* Baker and his colleagues report a less robust picture:

Approximately 40% of respondents with Internet access reported using the Internet to look for advice or information about health or healthcare in 2001. Six percent reported using e-mail to contact a physician or other health care professional. About one third of those using the Internet for health reported that using the Internet affected a decision about health or their health care, but very few reported impacts on measurable health care utilization; 94% said that Internet use had no effect on the number of physician visits they had and 93% said it had no effect on the number of telephone contacts. Five percent or less reported use of the Internet to obtain prescriptions or purchase pharmaceutical products.

Laurence Baker et al., *Use of the Internet and E-mail for Health Care Information: Results from a National Survey*, 289 JAMA 2400 (2003).

their physicians to ask questions, fix appointments, refill prescriptions, and receive test results.<sup>279</sup> A significant number aspire for a more robust experience, wanting more information on drug interactions, access to their electronic patient records, and increased availability of home or mobile diagnostic tools.<sup>280</sup> A 2003 survey found that thirty-seven percent of connected and relatively affluent patients were prepared to pay modest subscription or per-email fees in order to have online interaction with their physicians.<sup>281</sup>

Six million U.S. adults have purchased prescription drugs online.<sup>282</sup> The drugs most often bought online were Lipitor<sup>283</sup> for lowering cholesterol, Viagra<sup>284</sup> for erectile dysfunction, and Celebrex,<sup>285</sup> a pain reliever.<sup>286</sup> Seventy per cent of online purchases were for drugs previously prescribed in the course of a conventional physician-patient relationship.<sup>287</sup> The overwhelming majority of purchasers reported being equally satisfied (56%) or more satisfied (34%) than they were with purchases from a traditional pharmacy,<sup>288</sup> although a majority believed that buying drugs online is much more dangerous (39%) or somewhat more dangerous (22%) than buying them from a pharmacy.<sup>289</sup>

Online prescribing and dispensing no doubt attract customers for many of the same reasons that make other business-to-consumer storefronts so popular: convenience, round-the-clock availability,

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279. *Fast Facts*, RelayHealth, at <http://www.relayhealth.com/rh/general/news/fastFacts.aspx> (last visited July 29, 2004) (citing Harris Interactive poll from April 2002).

280. See FOX & FALLOWS, *supra* note 54, at 29.

281. Harris Interactive, *Patient/Physician Online Communication: Many Patients Want It, Would Pay for It, and It Would Influence Their Choice of Doctors and Health Plans*, HEALTH CARE NEWS, Apr. 10, 2002, [http://www.harrisinteractive.com/news/newsletters/healthnews/HI\\_HealthCareNews2002Vol2\\_Iss08.pdf](http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2002Vol2_Iss08.pdf).

282. Harris Interactive, *Six Million People Have Bought Prescription Drugs Online; Most Are Satisfied*, HEALTH CARE POLL, Mar. 23, 2004, [http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline\\_HI\\_Health-CarePoll2004vol3\\_iss06.pdf](http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline_HI_Health-CarePoll2004vol3_iss06.pdf).

283. Lipitor, at <http://www.lipitor.com/> (last visited Apr. 17, 2004).

284. Viagra, at <http://www.viagra.com/> (last visited Apr. 17, 2004).

285. Celebrex, at <http://www.celebrex.com/> (last visited Apr. 17, 2004).

286. Harris Interactive, *supra* note 282, at 3 tbl.5.

287. *Id.* at 2 tbl.2.

288. *Id.* tbl.3.

289. *Id.* tbl.4.

comparison-shopping, and variety. It is more difficult to assess what factors specifically motivate Internet prescribing. As discussed earlier, anecdotal evidence suggests that lower prices may not be as strong a factor as it is in other forms of online retailing, although it may still be a consumer aspiration. Rather, the specific “convenience” sought by those who purchase prescriptions online is the circumvention of the conventional physician-patient relationship. Some patients will go online following a refusal by their usual physician to prescribe a particular drug because of, for example, off-label use or the potential for abuse. Those seeking lifestyle drugs no doubt seek a level of anonymity or confidentiality that they assume to be missing from the traditional office visit. Similar factors probably explain patient interest in online fulfillment, although the cost factor is more complex. Customers of lifestyle drugs already face considerable “sticker shock” because such drugs are infrequently included in health plan formularies.<sup>290</sup> Patients who purchase from online pharmacies without a previously-issued orthodox prescription will seldom see significant savings over the local bricks-and-mortar pharmacy price and, counter-intuitively, may even find premium pricing.<sup>291</sup> In contrast, we know that seniors equipped with bricks-and-mortar prescriptions using the Canadian connection are doing so almost exclusively because of significant cost savings.<sup>292</sup>

There may be a more deep-seated, long-term, and disruptive basis for patient interest in online medicine and other controversial pharmaceutical channels. There are detectable signs of a fundamental shift in patient perspectives on prescribing and dispensing. Concomitant with their growing appetite for alternative medicine,<sup>293</sup> patients may be losing confidence in, and respect for, the traditional prescribing process, and hence its moral imperative. They view the transfer of drugs from legend to over the counter status as a function of expiring patents and perceive restrictive managed care formularies to be in stark contrast to the direct-to-consumer pharmaceutical advertising with which they are deluged and the free samples with which they are plied. Although a majority of patients still trust their personal physicians “to do the right thing for them personally

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290. See *Harrow v. Prudential Ins. Co. of Am.*, 279 F.3d 244 (3d Cir. 2002) (unsuccessful action by consumer against health plan that refused to cover Viagra).

291. See *supra* note 231 and accompanying text.

292. See *supra* note 138 and accompanying text.

293. See Sheryl Gay Stolberg, *Alternative Care Gains a Foothold*, N.Y. TIMES, Jan. 31, 2000, at A1; see also Kathleen M. Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J. L. & MED. 185 (1998); Nat'l Insts. of Health, *What Is Complementary and Alternative Medicine (CAM)?*, at <http://nccam.nih.gov/health/whatiscam/> (May 2002).

and for their health care,<sup>294</sup> they are more skeptical about interactions involving pharmaceuticals.<sup>295</sup> Increasingly, patients view their physicians' prescribing decisions as being driven by formulary rules rather than their needs; the traditional prescribing process and dispensing process is no longer viewed as providing access, but rather of erecting barriers.<sup>296</sup>

## V. RECURRING REGULATORY THEMES

In law and practice the "interlocking trellis"<sup>297</sup> of regulation that applies to interstate prescribing and dispensing often appears inconsistent and uncoordinated. More significantly, the way that our regulatory matrix deals unhappily with the supply of pharmaceuticals is suggestive of a difficult regulatory future for the broader e-health domain.

### A. Uneasy Federalism

First generation legal scholarship about the Internet was quick to point out the inherent difficulties of applying extant geographically "zoned" regulation to geographically incoherent cyberspace.<sup>298</sup> The

294. Harris Interactive, *Health-Care Professionals, Pharmacies, Hospitals Gain the Public's Top Trust* (Jan. 28, 2004), [http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline\\_HI\\_Health-CarePoll2004vol3\\_iss02.pdf](http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline_HI_Health-CarePoll2004vol3_iss02.pdf) (reporting sixty-three percent of patients so trusted their physicians).

295. *Id.* Forty-nine percent trust their pharmacies; forty-four percent trust their drugs; and fourteen percent trust pharmaceutical companies. *Id.* at 2.

296. One study reported, "The more money people spend out of pocket on drugs, the more likely they are to shop abroad. Fully 16 percent of those with out-of-pocket costs for drugs of over \$1,000 a year have shopped abroad." Harris Interactive, *Drug Companies May Be Headed for a Bruising Battle as Drug Importation Grows* (Oct. 9, 2003), [http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline\\_HI\\_Health-CarePoll2003vol2\\_iss8.pdf](http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline_HI_Health-CarePoll2003vol2_iss8.pdf).

297. *State v. Rasmussen*, 213 N.W.2d 661, 665 (Iowa 1973).

298. See, e.g., David R. Johnson & David Post, *Law and Borders—The Rise of Law in Cyberspace*, 48 STAN. L. REV. 1367, 1375 (1996); David G. Post, *Governing Cyberspace*, 43 WAYNE L. REV. 155 (1996); Joanna Zakalik, *Law Without Borders in Cyberspace*, 43 WAYNE L. REV. 101 (1996). See generally LAWRENCE LESSIG, *CODE AND OTHER LAWS OF CYBERSPACE* 24-29 (1999). For contemporary analysis, see Goldsmith, *supra* note 272, at 1250 ("There is no general normative argument that supports the immunization of cyberspace activities from territorial regulation. And there is every reason to believe that nations can exercise territorial authority to achieve significant regulatory control over cyberspace transactions."); Dan Hunter, *Cyberspace as Place and the Tragedy of the Digital Anticommons*, 91 CAL. L. REV. 439

avoidance of concrete examples by local social policies, such as those restricting gambling and pornography, has highlighted the tensions between state and federal systems.<sup>299</sup> The issues surrounding interstate Internet traffic have not been lost on those commenting on the growth of telemedicine and other forms of technologically-mediated care.<sup>300</sup>

The uneasy, or perhaps fragile, federalism that regulates the online health domain is largely a function of the historical divide between federal and state regulation of healthcare. After *Dent v. West Virginia*<sup>301</sup> established the legitimacy and primacy of state regulation of health professionals and the passage of the FDCA by Congress,<sup>302</sup> the stage was set for dichotomized regulation of approval and distribution. The escalating regulatory landscape at both federal<sup>303</sup> and state<sup>304</sup> levels has managed to simultaneously blur and confirm this dichotomy. Such a patchwork of regulation of the largest industry in the United States<sup>305</sup> is both inefficient and strained in the face of a developing market for interstate, technologically mediated care.

### 1. Inconsistencies and Inefficiencies

Federal and state health policies and regulations frequently seem disharmonized and inconsistent. Health privacy is just one example. The existing patchwork of state common law privacy and confidentiality rules

(2003); and Mark A. Lemley, *Place and Cyberspace*, 91 CAL. L. REV. 521 (2003).

299. See, e.g., Charles R. Topping, *The Surf Is Up, but Who Owns the Beach?—Who Should Regulate Commerce on the Internet?*, 13 NOTRE DAME J.L. ETHICS & PUB. POL'Y 179 (1999); Stevie A. Kish, Note, *Betting on the Net: An Analysis of the Government's Role in Addressing Internet Gambling*, 51 FED. COMM. L.J. 449 (1999).

300. See, e.g., Ross D. Silverman, *Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards*, 26 AM. J.L. & MED. 255 (2000); P. Greg Gulick, *E-Health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural, and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs*, 12 ALB. L.J. SCI. & TECH. 351 (2002).

301. See *supra* note 33 and accompanying text.

302. 21 U.S.C. § 355(a) (2000).

303. The federal regulatory framework includes the FDA, DEA, FTC, Centers for Medicare and Medicaid Services (CMS), and an array of federal reporting, fraud, and abuse laws.

304. Malpractice doctrine, privacy laws, state controlled substances law, as well as state fraud and abuse laws make up the state regulatory framework.

305. In 2001, the U.S. bill for healthcare was \$1.4 trillion (14.1 percent of GDP). See *American Health Care: Why So Costly?: Hearing Before the Subcomm. on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Comm.*, 108th Cong. 6 (2003) (testimony of Karen Davis & Barbara S. Cooper, The Commonwealth Fund).

were insufficient to promote consumer confidence in the growing national health infrastructure. Yet, deficiencies in the resulting federal law cheated the Centers for Medicare and Medicaid Services (CMS) out of the power to create a truly comprehensive federal privacy system that superceded and improved upon state privacy protections. As a result, the federal Privacy of Individually Identifiable Health Information (PIHI) regulations made under HIPAA featured what is sometimes called cooperative preemption, which sets a federal floor that states may exceed.<sup>306</sup> As flaws in the PIHI regulations became more obvious and the Bush Administration reduced federal requirements,<sup>307</sup> the gap between the federal floor and the more stringent state law became evident, and privacy advocates looked to the states to carry the federal flag of reducing patient privacy costs externalized by providers.

Such differences between state and federal law, coupled with interstate inconsistencies, jeopardize efficient workings of national markets for technologically-mediated healthcare. The FTC has expressed particular interest in “state and local regulations, such as occupational licensing and physical office requirements, that may have pro-consumer and pro-competition goals, but that nevertheless may restrict the entry of new Internet competitors or hamper their operations.”<sup>308</sup> One of the businesses explicitly on the FTC radar is “Healthcare, Pharmaceuticals, and Telemedicine.”<sup>309</sup> The agency has already weighed in on Connecticut’s attempts to regulate cross-border sales of replacement prescription contact lenses. It found that requiring sellers of replacement contact lenses to obtain Connecticut optician and optical licenses would harm the public health by increasing costs. Those increased costs would in turn result in people replacing their contacts less frequently than recommended.<sup>310</sup> Similarly, in its report on online interstate sales of wine, the FTC

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306. 45 C.F.R. §§ 160.201-.205 (2003).

307. An example is removing any requirements of consent for data used for TPO purposes. *Id.* § 164.506.

308. *Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the House Comm. on Energy and Commerce*, 107th Cong. (2002) (prepared statement of Ted Cruz, Director of the Office of Policy Planning, Federal Trade Commission); see Virginia Postnel, *A Look at Wine Sales over the Internet Shows the Price of Some Regulations in the Name of Consumer Protection*, N.Y. TIMES, July 17, 2003, at C2.

309. *Id.*

310. In Re: Declaratory Ruling Proceeding on the Interpretation and Applicability of Various Statutes and Regulations Concerning the Sale of Contact Lenses, Comments of the Staff of the Federal Trade Commission, Intervenor (Mar. 27, 2002), <http://www.ftc.gov/be/v020007.htm>.



concluded that “consumers could reap significant benefits if they had the option of purchasing wine online from out-of-state sources and having it shipped directly to them. Consumers could save money, choose from a much greater variety of wines, and enjoy the convenience of home delivery.”<sup>311</sup> The agency also noted that where such bans have been successfully challenged “states appear to have found means of satisfying their tax and other regulatory goals that are less restrictive than an outright ban.”<sup>312</sup>

From questions posed by the agency to prescribing and dispensing stakeholders, it seems clear that the FTC is attempting to assess the degree to which medical licensure laws have chilled interstate drug traffic.<sup>313</sup> What remains to be seen is whether the Commission can be persuaded of the benefits of online healthcare and the importance of a national e-health market, or if states can achieve their public health policies associated with pharmaceutical distribution with regulation that is less restrictive than framed local licensure.

## 2. *The Specter of the Dormant Commerce Clause*

This picture of uneasy federalism in the United States exists beyond political and economic domains. State regulation that discriminates between intrastate and interstate e-health scenarios may face constitutional challenge.<sup>314</sup> The Commerce Clause that gives Congress the power to regulate commerce “among the several States”<sup>315</sup> not only grants interstate powers to Congress but also has a “dormant” or “reverse” aspect that limits the power of the states to regulate interstate commerce.<sup>316</sup> No court has

311. FED. TRADE COMM’N, POSSIBLE ANTICOMPETITIVE BARRIERS TO E-COMMERCE: WINE 4 (2003), <http://www.ftc.gov/os/2003/07/winereport2.pdf>.

312. *Id.*

313. FED. TRADE COMM’N, PUBLIC WORKSHOP: POSSIBLE ANTICOMPETITIVE EFFECTS TO RESTRICT COMPETITION ON THE INTERNET, FOURTH SESSION—TELEMEDICINE AND ONLINE PHARMACEUTICAL SALES 593-664 (2002) [hereinafter PUBLIC WORKSHOP], <http://www.ftc.gov/opp/ecommerce/anticompetitive/021009antitrans.pdf>.

314. In addition to the Commerce Clause arguments discussed in this Section a clumsily-worded state law could infringe the Privileges and Immunities Clause if it insisted on, for example, the residence of a physician in the state as a condition of licensure. *See supra* note 40.

315. U.S. CONST. art. I, § 8, cl. 3.

316. *See, e.g., Oregon Waste Sys. v. Dep’t of Env’tl. Quality*, 511 U.S. 93 (1994); *Dennis v. Higgins*, 498 U.S. 439, 447 (1991); *Passenger Cases*, 48 U.S. (7 How.) 283 (1849); *Willson v. Black Bird Creek Marsh Co.*, 27 U.S. (2 Pet.) 245 (1829). The court in *Kassel v. Consolidated*

considered the constitutionality of state statutes that seek to regulate Internet prescribing or dispensing.<sup>317</sup> Notwithstanding recent judicial approval of state spam regulation,<sup>318</sup> decisions striking down state laws regulating interstate e-commerce in wine<sup>319</sup> and protected speech<sup>320</sup> suggest that overreaching legislative activity affecting cross-border prescribing or dispensing could face serious constitutional challenge.

While the possibility of a dormant commerce clause challenge is easy to state, the resolution of such a challenge is far more difficult to predict. First, modern scholarship has identified judicial overreaching in the early e-commerce cases, particularly in cases that rely on “chilling” or “inconsistent regulation” analysis.<sup>321</sup> Second, dormant commerce clause jurisprudence is replete with deferential references to “state legislation in the field of safety where the propriety of local regulation has long been recognized.”<sup>322</sup> Third, there is a threshold question, related to the second

*Frieghtways Corp.* stated that “[t]he Clause requires that some aspects of trade generally must remain free from interference by the States. When a State ventures excessively into the regulation of these aspects of commerce, it ‘trespasses upon national interests’ . . . and the courts will hold the state regulation invalid under the Clause alone.” 450 U.S. 662, 669 (1981) (internal citations omitted).

317. *Cf. Nat’l Pharms. v. Feliciano-de-Melecio*, 221 F.3d 235 (1st Cir. 2000) (interpreting a Puerto Rican pharmacy statute as not applying to mail-order pharmacies based outside of Puerto Rico and therefore not reaching the constitutional issues). Pre-Internet cases are discussed below. *See infra* text accompanying note 331-336.

318. *See, e.g., Ferguson v. Friendfinders, Inc.*, 115 Cal. Rptr. 2d 258 (Ct. App. 2002) (holding that a statute governing unsolicited commercial e-mail does not unconstitutionally burden interstate commerce).

319. *See, e.g., Dickerson v. Bailey*, 212 F. Supp. 2d 673 (S.D. Tex. 2002) (holding that Texas Alcoholic Beverage Code that allowed consumers to purchase wines from Texas wineries and to have the wines shipped to their homes, but expressly prohibited such activity as to out-of-state wineries, violated the dormant Commerce Clause); *see also Heald v. Engler*, 342 F.3d 517 (6th Cir. 2003); *Bolick v. Danielson*, 330 F.3d 274 (4th Cir. 2003); *Beskind v. Easley*, 325 F.3d 506 (4th Cir. 2003); *Swedenburg v. Kelly*, 232 F. Supp. 2d 135 (S.D.N.Y. 2002).

320. *See, e.g., Am. Booksellers Found. for Free Expression v. Dean*, 202 F. Supp. 2d 300 (D. Vt. 2002).

321. Goldsmith & Sykes, *Dormant Commerce Clause*, *supra* note 221; *see also* James E. Gaylord, Note, *State Regulatory Jurisdiction and the Internet: Letting the Dormant Commerce Clause Lie*, 52 VAND. L. REV. 1095 (1999).

322. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 143 (1970) (citing *S. Pac. Co. v. Arizona*, 325 U.S. 761, 796 (Douglas, J., dissenting)). *But see Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 670 (1981) (“[T]he incantation of a purpose to promote the public health or safety does not insulate a state law from Commerce Clause attack. Regulations

reservation, as to whether commerce clause analysis appropriately applies to dangerous or impure goods or services that clearly will be the targets of some state Internet prescribing and dispensing regulation.<sup>323</sup> Fourth, in challenges to state prescribing and dispensing regulation, the courts will likely attempt to avoid the constitutional question by first attempting to interpret the suspect state law as having only intrastate effects.<sup>324</sup>

Traditionally explained, dormant commerce clause analysis distinguishes between state regulation that impinges on cross-border commerce and regulation that facially discriminates between interstate and intrastate commerce. The former is assessed under a balancing test,<sup>325</sup> while the latter is assessed under strict scrutiny.<sup>326</sup> Therefore, the first challenge is to identify the correct test for the various types of Internet prescribing and dispensing regulation that may be confronted. The majority of state e-health law is not facially discriminatory. This seems to be the case with state laws that require physicians who are engaged in the “practice of medicine” within the state to be licensed or to have telemedicine practice certificates. In such cases, the out-of-state physician resisting such “foreign” regulation presumably would have to argue that the state requirement of licensure impinges on cross-border commerce. If the state law contains granular consent requirements, the argument could be extended to allege inconsistent regulation premised on multiple state laws requiring, for

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designed for that salutary purpose nevertheless may further the purpose so marginally, and interfere with commerce so substantially, as to be invalid under the Commerce Clause.”).

323. *Pike*, 397 U.S. at 143; see also *Sligh v. Kirkwood*, 237 U.S. 52, 59-60 (1915).

324. See, e.g., *Nat’l Pharms. v. De Melecio*, 221 F.3d 235 (1st Cir. 2000). A direct-indirect burdens test may also be used. “Occasionally the Court has candidly undertaken a balancing approach in resolving these issues, but more frequently it has spoken in terms of “direct” and “indirect” effects and burdens.” *Pike*, 397 U.S. at 142 (internal citations omitted).

325. In *Pike*, the court noted:

Although the criteria for determining the validity of state statutes affecting interstate commerce have been variously stated, the general rule that emerges can be phrased as follows: Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

*Id.* at 142 (internal citation omitted).

326. *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662 (1981).

example, different consent specifics. Applying a balancing analysis, including deference to state public health interests, and assuming that the state would argue that the physician or pharmacist was capable of identifying the residence of the patient, it would be a brave court that would strike down such local regulation on Commerce Clause grounds.<sup>327</sup>

In contrast, strict scrutiny could well apply to state regulations that differentiate between intrastate and interstate activities. For example, Montana applies its telemedicine-specific regulation only to interstate exchanges between physician and patient,<sup>328</sup> and West Virginia defines the "practice of telemedicine" as diagnosis or treatment by out-of-state physicians,<sup>329</sup> while several states now require their local pharmacists to reject or further investigate (and hence chill the market in) Internet (and typically interstate) prescriptions.<sup>330</sup>

Pre-Internet bricks-and-mortar and mail order decisions contribute little to the analysis. However, in *State v. Rasmussen*,<sup>331</sup> an Iowa pharmacy challenged a state law that made it unlawful for the pharmacy to dispense prescriptions written by out-of-state physicians who were not licensed in Iowa. The court rejected strict scrutiny because the "Iowa statute does not discriminate in its language between foreign practitioners and those registered in Iowa—all are required to register under the provisions of the Iowa Act in order to dispense drugs in Iowa."<sup>332</sup> Due to its indirect protectionist effects, the court still viewed the regulation as constitutionally infirm under a balancing test.<sup>333</sup> Given that the state-federal regulatory mix was more sophisticated and structured than anything seen to date in the Internet prescribing or dispensing domains (the Iowa statute was passed pursuant to the Uniform Controlled Substances Act<sup>334</sup> and synchronized with the federal Comprehensive Drug Abuse Prevention and Control Act of 1970<sup>335</sup> implicitly

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327. See Tenn. Op. Atty. Gen. No. 98-202, 1998 WL 851333 (Oct. 28, 1998). An alternative set of arguments could apply in the case of a First Amendment argument. See generally Gaylord, *supra* note 321.

328. MONT. CODE ANN. § 37-3-342 (2003).

329. W. VA. CODE ANN. § 30-3-13 (Michie 2002).

330. CAL. BUS. & PROF. CODE § 2242.1(b) (West 2003); TEX. ADMIN. CODE §§ 291.34, 291.36 (West 2004).

331. 213 N.W.2d 661 (Iowa 1973).

332. *Id.* at 667.

333. *Id.* at 667-68; cf. *Nichols v. Bd. of Pharm.*, 657 P.2d 216 (Or. Ct. App. 1983) (holding that an Oregon statute which permitted pharmacies to fill only prescriptions written by practitioners licensed only in Oregon was not in "positive conflict" with federal law).

334. UNIFORM CONTROLLED SUBSTANCES ACT (1994).

335. 21 U.S.C. § 801(a) (2000).

reducing the role of state-based regulation of interstate activities), some might argue that a limited reading of *Rasmussen* is appropriate. Nonetheless, *Rasmussen* is familiar to state attorneys general and clearly informs some conservative opinions warning state legislatures to stay clear of protectionist policies or interstate regulation.<sup>336</sup>

### *B. The Failure of Self-Regulation*

Various types of self or private regulation have been promoted as a solution to emerging issues in technologically-mediated care. This is consistent with the broader world of Internet interaction and e-commerce. There, the call for self-regulation has been a product of: 1) utopian views of how cyberspace regulation *should* be disconnected from traditional regulation;<sup>337</sup> 2) a desire not to impede e-commerce with extensive governmental regulation; and 3) a reflection of the general lack of preparedness of traditional regulatory standards and agencies to deal with Internet phenomena. In the health arena, self-regulation is of particular significance because of the historical impact of American Medical Association (AMA) ethical standards and, more narrowly, because of the frequently praised VIPPS accreditation system.<sup>338</sup>

Four types of self-regulatory systems have demonstrated traction in the e-health domain. The first system is purely aspirational: a code of conduct promulgated by some group, often a not-for-profit organization, with a hope of voluntary compliance.<sup>339</sup> Obviously, codes that are promulgated by important stakeholders or that reach a critical mass of adopters tend to be more effective in catching the attention of consumers and attracting further adopters. Typically, compliance is voluntary and not policed. The second system is one that signifies participation in the self-regulatory process by making available a "kitemark" or "trustmark."<sup>340</sup> Such a scheme

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336. See, e.g., Tex. Atty. Gen. Op. JM-555, 1986 WL 219401.

337. As Dan Hunter puts it, "[T]he received wisdom has confused the descriptive question of whether we think of cyberspace as a place with the normative question of whether we should regulate cyberspace as a regime independent of national laws." Hunter, *supra* note 298, at 443.

338. For more information on the accreditation system, see VIPPS, at <http://www.nabp.net/vipps/> (last visited Apr. 17, 2004).

339. See, e.g., *eHealth Code of Ethics*, Internet Healthcare Coalition, at <http://www.ihealthcoalition.org/ethics/ehcode.html> (last visited Apr. 17, 2004); *Hi-Ethics Ethical Principles For Offering Internet Health Services to Consumers*, Hi-Ethics, at <http://www.hiethics.org/Principles/index.asp> (Apr. 17, 2004).

340. See, e.g., The Health on the Net Foundation (HonCode), at <http://www.hon.ch> (last

assumes the existence of a rudimentary code authority that owns the intellectual property in the trustmark and, at least in theory, will act to stop fraudulent use of the trustmark or its continued use by those out of code compliance. Along with the simpler code model, it is primarily dependent upon self-rating and, as the number of adopters grows, the likelihood of non-compliance will increase.<sup>341</sup>

The third type of system is a variant of the second, except that it is not wholly dependent upon self-rating. The scheme uses either a centralized or peer (de-centralized) system that applies (or checks the application of) the code's quality criteria.<sup>342</sup> It is not necessarily self-regulatory or voluntary in that the rating authority may apply quality criteria regardless of the content owner's wishes, a characteristic that is itself the source of potential legal problems.<sup>343</sup> The fourth type of system is a code that operates contemporaneously with an existing membership or ethically-constraining system, such as when a medical society issues guidelines for how its membership might navigate particular web or email issues.<sup>344</sup>

Some codes of conduct that associate membership or compliance with a data object (such as a trustmark or an Internet domain such as dot.health) attempt to increase their robustness and penetration by leveraging web technologies. Again, there are several models. For example, a trustmark system whose data object complies with the Platform for

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visited Apr. 17, 2004); Truste, eHealth Privacy Seal Program, *at* [http://www.truste.org/programs/pub\\_ehealth.html](http://www.truste.org/programs/pub_ehealth.html) (last visited Apr. 17, 2004).

341. There are two reasons for this decline in compliance: First, the larger the number of adopters the higher are the costs of discovering non-compliance; second, as the number of adopters grows so more marginal players will be attracted to the model because the trustmark will have increasing market-access or marketing value.

342. *See, e.g.*, About MedCIRCLE, MedCIRCLE, *at* <http://www.medcircle.org/about.php?lanxid=641562d82ald56a797812c7f0dfabb2d> (last visited Apr. 17, 2004).

343. *See generally* Nicolas P. Terry, *Rating the "Raters": Legal Exposure of Trustmark Authorities in the Context of Consumer Health Informatics*, *at* 2 J. MED. INTERNET RES. e18 (2000), *available at* <http://www.jmir.org/2000/3/e18/>.

344. *See, e.g.*, AM. MED. ASS'N, ETHICAL GUIDELINES FOR THE USE OF ELECTRONIC MAIL BETWEEN PATIENTS AND PHYSICIANS (CEJA Report 3-I-02, 2002) [hereinafter AM. MED. ASS'N, ETHICAL GUIDELINES], [http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja\\_report\\_3i02.pdf](http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_report_3i02.pdf); Press Release, Am. Med. Ass'n, AMA Adopts New Guidelines To Help Physicians Ensure Safe and Secure Internet Prescribing (June 19, 2003) [hereinafter AMA Adopts], <http://www.ama-assn.org/ama/pub/article/1616-7802.html>.

Internet Content (PICS) specifications<sup>345</sup> could leverage “downstream filtering,”<sup>346</sup> allowing a patient to use browser or third party software to rate or exclude content by reference to the data object.<sup>347</sup> A second type is “upstream filtering,” which is more likely to leverage a distinct “top-level domain” (TLD),<sup>348</sup> a system favored by the World Health Organization.<sup>349</sup> Assume, for example, that only certain health content providers (e.g., professional bodies or peer-reviewed sites) would be granted a *.health* TLD name. Then web directories could list them separately or search engines could prioritize them in search results. A third type of technology layer added to self-regulatory systems may be described as closed-loop verification. Most trustmark systems allow or compel the trustmark user to “link” the trustmark: Rudimentary systems link back to the trustmark authority’s principles or code of conduct. More sophisticated systems, however, close the loop by linking to a specific page on the trustmark authority’s site that verifies the good standing of the trustmark user.<sup>350</sup> Such an interlinking model decreases fraudulent use of the trustmark and encourages code compliance by facilitating consumer feedback to the trustmark authority.

### 1. Content Regulation

The integrity and reliability of Internet health information has been of acute concern to the medical profession,<sup>351</sup> although patients seem to be

345. PICS is a specification frequently used in filtering applications and allows labels to be associated with specific internet content.

346. Filtering generally will likely become more common on the web following the Supreme Court’s opinion in *United States v. Am. Library Ass’n, Inc.*, 123 S. Ct. 2297 (2003) (upholding Children’s Internet Protection Act that conditioned federal assistance of public libraries on the installation of filtering software to block obscene or pornographic images).

347. See, e.g., MedCIRCLE, at <http://www.medcircle.org/> (last visited Apr. 17, 2004).

348. See ICANN, at <http://www.icann.org/tlds/> (last visited Apr. 17, 2004).

349. *TLD Application for .health*, ICANN, at <http://www.icann.org/tlds/health1/> (last visited Apr. 17, 2004). The WHO’s initial application was denied, but is being renewed. See *Domain Firms Get Second Shot at ICANN Approval*, COMPUTERWIRE, June 25, 2003.

350. See, e.g., healthAtoZ, at <http://www.healthatoz.com/> (last visited Apr. 17, 2004) (linking to its HONCode verification page at <http://www.hon.ch/HONcode/Conduct.html?HONConduct386169>).

351. See *Site Reading Physicians Grapple with Recommending Web Sites*, AMNews, at [http://www.ama-assn.org/sci-pubs/amnews/pick\\_00/tesa1023.htm](http://www.ama-assn.org/sci-pubs/amnews/pick_00/tesa1023.htm) (Oct. 23/30, 2000); see also Berland et al., *Health Information on the Internet: Accessibility, Quality, and Readability in English and Spanish*, 285 JAMA 2612 (2001); KM Griffiths & H. Helen Christensen, *Quality of Web Based Information on Treatment of Depression: Cross Sectional Survey*, 321 BRIT. MED. J. 1511

more accepting of the medium's flaws.<sup>352</sup> The pursuit of Internet content quality assurance exists in something of a legal vacuum. Public law intervention tends to be limited to obviously dangerous health content where government agencies<sup>353</sup> can apply their traditional consumer protection, drug regulation, and fraud powers.<sup>354</sup> More robust public law regulation or private litigation is likely to conflict with guarantees of free speech.<sup>355</sup> Several well-known codes of conduct have sought to fill this vacuum.<sup>356</sup> Specifically, the European Commission has endorsed this approach by publishing its own "Quality Criteria for Health Related Websites."<sup>357</sup>

In the area of medical web content, the focus of self-regulatory systems has been to strengthen the role of the market by reducing the patient's information costs regarding the integrity and reliability of health information on the web. Such improvements could positively influence the growth of, and regulatory attitudes towards, Internet prescribing and dispensing because prescribing sites tend to contain medical and health information and content sites frequently link to prescribing or fulfillment sites.

Unfortunately, the self-regulatory content system is dangerously flawed. Trustmarks are easily copied and pasted into non-compliant sites with the link back to the trustmark authority conveniently omitted. Content and prescribing sites also use counterfeit trustmarks that resemble well-known trustmarks. There are also no constraints on who can create a

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(2000), <http://www.bmj.com/cgi/content/full/321/7275/1511>.

352. *Cyberchondriacs Continue To Grow in America*, HEALTH CARE NEWS, May 8, 2002, [http://www.harrisinteractive.com/news/newsletters/healthnews/HI\\_HealthCareNews2002Vol2\\_Iss09.pdf](http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2002Vol2_Iss09.pdf). According to a Harris Interactive survey in 2000, fifty-six percent of respondents were of the opinion that the Internet helped them gain an understanding of their health problems; this compares to seventy-three percent in the 1999 survey. There were also declines in how patients viewed the Internet as helping them manage their personal healthcare overall (sixty percent down to forty-one percent) and communicate with their doctor (fifty-one percent down to twenty-nine percent).

353. See, e.g., Press Release, Fed. Trade Comm'n, Eli Lilly Settles FTC Charges Concerning Security Breach (Jan. 18, 2002), <http://www.ftc.gov/opa/2002/01/elililly.htm>.

354. See *supra* notes 235-242 and accompanying text.

355. See Nicolas P. Terry, *Cyber-Malpractice: Legal Exposure for Cybermedicine*, 25 AM. J.L. & MED. 327 (1999).

356. See *supra* notes 339-340.

357. *Quality Criteria for Health Related Websites*, Information Society, at [http://europa.eu.int/information\\_society/europe/ehealth/quality/draft\\_guidelines/index\\_en.htm](http://europa.eu.int/information_society/europe/ehealth/quality/draft_guidelines/index_en.htm) (last visited Apr. 17, 2004).



self-regulatory or trustmark system. For example, the Council for Responsible Telemedicine (CRT)<sup>358</sup> was formed by three Internet prescribing companies that have been involved in several regulatory skirmishes with state boards. The AMA was less than impressed by the CRT's position on supplying lifestyle drugs.<sup>359</sup> Even assuming that a trustmark is valid and that users accurately self-rate themselves, the sheer shallowness of most self-regulatory standards creates concern.<sup>360</sup> Overall, it is arguable that all benefits to patients from self-regulatory codes are outweighed by the risks of overconfidence generated by valid trustmarks or outright fraud from the counterfeit ones.

One system that has the potential to counter this negative conclusion is the Health Web Site Accreditation Program instituted by the Utilization Review Accreditation Commission (URAC).<sup>361</sup> There are several reasons for this optimism: the URAC standards are robust;<sup>362</sup> an accreditation model is substituted for suspect self-rating or unfunded and impractical external review; trustmark posting is subject to closed-loop verification; and URAC offers sophisticated downstream filtering via an external search engine.<sup>363</sup>

## 2. *The Physician-Patient Relationship*

As already noted, there has been considerable professional angst about the legal and ethical issues surrounding electronic communications between physicians and patients.<sup>364</sup> The most authoritative discussion of this issue has been the guidelines issued by the American Medical

358. Council for Responsible Telemedicine, at <http://www.councilforresponsibletelemedicine.org/> (last visited Apr. 17, 2004).

359. *Questions Linger over Group's "Responsible" Prescribing*, AMNews, at [http://www.ama-assn.org/sci-pubs/amnews/pick\\_02/bisc1014.htm](http://www.ama-assn.org/sci-pubs/amnews/pick_02/bisc1014.htm) (Oct. 14, 2002).

360. See, e.g., *HON Code of Conduct (HONcode) for Medical and Health Web Sites*, Health on the Net Foundation, at <http://www.hon.ch/HONcode/Conduct.html> (last visited Apr. 17, 2004).

361. URAC, at <http://webapps.urac.org/websiteaccreditation/default.htm> (last visited Apr. 17, 2004). URAC is also known as the American Accreditation HealthCare Commission.

362. *Health Web Site Standards*, URAC, at <http://webapps.urac.org/websiteaccreditation/Portal/Business/Docs/web%20site%20stds%20v1-0.doc> (last visited Apr. 17, 2004).

363. VitalSeek, at <http://www.vitalseek.com/> (last visited Apr. 17, 2004).

364. See *supra* notes 254-267 and accompanying text.

Informatics Association.<sup>365</sup> As with the more recent amendments to the AMA Ethics Policy,<sup>366</sup> these guidelines assume an existing physician-patient relationship.<sup>367</sup> The AMA policy seems even more restrictive, asserting that “[e]-mail correspondence should not be used to establish a patient-physician relationship. Rather, e-mail should supplement other, more personal, encounters.”<sup>368</sup>

That idea of enhancing an existing relationship, coupled with a firm belief that interpersonal interaction is at the core of the patient-physician relationship, has dominated the way the AMA has addressed online medicine. In the process, it has taken a position that has been consistently hostile to Internet prescribing and dispensing. For example, an AMA policy pledges that the organization will “work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet the local standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications.”<sup>369</sup> That same policy pledges to “work with federal and state regulatory bodies to close down Internet web sites of companies that are illegally promoting and distributing (selling) prescription drug products in the United States.”<sup>370</sup>

This approach was reiterated and expanded upon by AMA guidelines issued in 2003 that deal specifically with Internet prescribing. The Guidance for Physicians on Internet Prescribing endorses requiring licensure in the patient’s state of residence.<sup>371</sup> Further, it reiterates the AMA’s position that an existing physician-patient relationship and a physical examination are prerequisites for online prescribing.<sup>372</sup> In

365. *See supra* note 261.

366. AM. MED. ASS’N, ETHICAL GUIDELINES, *supra* note 344.

367. However, the American Medical Informatics Association’s (AMIA) guidelines use the more ambiguous term “contractual relationship.” *See supra* note 261.

368. CEJA REPORT, *supra* note 344, at para. 1.

369. AM. MED. ASS’N, H-120.956(3) INTERNET PRESCRIBING (BOT Rep. 35, A-99), [http://www.ama-](http://www.ama-assn.org/apps/pf_online/pf_online?f_n=browse&doc=policyfiles/HOD/H-120.956.HTM&&s_t=&st_p=&nth=I&prev_pol=policyfiles/HOD/H-115.997.HTM&nxt_pol=policyfiles/HOD/H-120.950.HTM&)

[assn.org/apps/pf\\_online/pf\\_online?f\\_n=browse&doc=policyfiles/HOD/H-120.956.HTM&&s\\_t=&st\\_p=&nth=I&prev\\_pol=policyfiles/HOD/H-115.997.HTM&nxt\\_pol=policyfiles/HOD/H-120.950.HTM&](http://www.ama-assn.org/apps/pf_online/pf_online?f_n=browse&doc=policyfiles/HOD/H-120.956.HTM&&s_t=&st_p=&nth=I&prev_pol=policyfiles/HOD/H-115.997.HTM&nxt_pol=policyfiles/HOD/H-120.950.HTM&).

370. *Id.* at H-120.956(6).

371. AM. MED. ASS’N, GUIDANCE FOR PHYSICIANS ON INTERNET PRESCRIBING (Resolution 518, A-02, 2003), <http://www.ama-assn.org/ama1/upload/mm/annual03/bot7a03.doc>; *see also* AMA Adopts, *supra* note 344.

372. AMA Adopts, *supra* note 344. The release states:

commentary, the guidelines state that “[w]eb sites that offer a prescription solely on the basis of an online questionnaire (or online consultation) with no other interaction between the physician and patient are insufficient.”<sup>373</sup> This type of regulation is typical of a code model that operates conterminously with a closed professional system. It is noticeably conservative and uncompromising in the hard position it takes towards online prescribing.

### 3. *Pharmacy Regulation and VIPPS*

The National Association of Boards of Pharmacy (NABP) has been no less hostile to Internet dispensing, but it has shown more interest in leveraging web technology to decrease patient information costs. Its well-known response to Internet dispensing and fulfillment is the Verified Internet Pharmacy Practice Sites, or “VIPPS,” program.<sup>374</sup> VIPPS is a code model that operates conterminously with the closed system of multi-state pharmacy licensure. Indeed, one state allows its Internet pharmacies to choose whether to display its state permit number or VIPPS trustmark.<sup>375</sup> VIPPS resembles an accreditation model, charging participants a fee and performing on-site physical inspection, complaint investigation, and periodic re-inspections.<sup>376</sup> Its trustmark uses closed-loop verification to reduce fraud.

David Brushwood has argued that “[p]romotion of the VIPPS program is the best assurance regulators can provide to the public that individual

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Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall: obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided; have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s); as appropriate, follow up with the patient to assess the therapeutic outcome; maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and include the electronic prescription information as part of the patient medical record.

*Id.*

373. *Id.*

374. VIPPS, at <http://www.nabp.net/vipps/intro.asp> (last visited Apr. 17, 2004).

375. ARK. CODE ANN. § 17-92-1005(4) (Michie 2002) (requiring Internet pharmacies to clearly display their state permit number or VIPPS seal on their internet site).

376. VIPPS® Certification Process, at <http://www.nabp.net/vipps/pharmacy/intro.asp> (last visited Apr. 17, 2004).

Internet pharmacy users are being protected by the professionalism that state-licensed pharmacists offer through their oversight of the medication use process.<sup>377</sup> While it is correct that VIPPS certification tells us something positive about the few accredited pharmacies, its absence tells us little about the level of risk that the consumer might expect when the pharmacy is not accredited.<sup>378</sup> Thus, VIPPS tends to confirm the status quo without substantially aiding patients who choose to operate outside of the traditional dispensing paradigm.

VIPPS has accredited relatively few sites.<sup>379</sup> VIPPS's apparent requirement of licensure in the patient's state of residence means that, as presently constituted, it is not a solution to the Internet dispensing conundrum, as evidenced by the chilly reception given by Canadian Internet pharmacies towards proposals to extend the program north of the border.<sup>380</sup>

### *C. Under-regulation: Patient Incurred Costs*

The goal of medical and pharmacy licensure systems is to promote provider quality and patient safety. In practice, however, the state board processes tend to concentrate on the more inter-personal aspects of the physician-patient relationship,<sup>381</sup> and when quality is addressed, it is done retrospectively.<sup>382</sup> The healthcare system continues to externalize most of its quality and safety risks to patients. This is exacerbated in the areas of Internet prescribing and dispensing, in which regulators concentrate on the method of providing services: technology, questionnaire prescribing, and importation. In practice, patients seeking online care face considerable privacy and quality risks. In Internet prescribing and

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377. Brushwood, *supra* note 268, at 102-03.

378. An absolutist would argue that absent accreditation, the risk is too high. A relativist interested in the market determining the better or safer online unaccredited pharmacists would need more than a null response.

379. See *VIPPS Database Search Results*, at <http://www.nabp.net/vipps/consumer/listall.asp> (last visited Apr. 17, 2004).

380. See, e.g., Carl Bialik, *U.S., Canada Pharmacy Groups Seek To Deter Exporting of Drugs*, WALL ST. J., Nov. 13, 2002, at D3.

381. 1 AVEDIS DONABEDIAN, *THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT* 4 (1980) ("Technical care is the application of the science and technology of medicine, and of the other health sciences, to the management of a personal health problem. Its accompaniment is the management of the social and psychological interaction between client and practitioner.").

382. See Leape, *supra* note 220.

dispensing, these risks are undervalued and under-regulated.

### 1. *The Privacy Externality*

As with other information domains, technology has dramatically changed the way patient health data is acquired, stored, aggregated, processed, accessed, and distributed. Additionally, there are inherent tensions in the health information domain between the key stakeholders and their needs: government access and security for public health;<sup>383</sup> healthcare institutions' access for quality assurance and marketing; and patient interests in confidentiality, privacy, and anonymity.<sup>384</sup>

Few pieces of legislation or regulation in contemporary healthcare law have been as controversial as the privacy<sup>385</sup> and security<sup>386</sup> regulations promulgated under HIPAA.<sup>387</sup> Designed to force providers to internalize privacy and security risks associated with technologically-mediated care, record-keeping, and billing, the HIPAA regulations are primarily applicable to bricks-and-mortar care providers.<sup>388</sup> Technical limitations in the HIPAA statute were primarily responsible for this limitation,<sup>389</sup> though it is also the case that, principally, the regulations were drafted prior to the explosive growth of Internet prescribing and dispensing. Conceptually, the PIHI standards, as they exist today, are similar to, but not co-extensive with, the statutory controls that exist in a small minority of U.S. states,<sup>390</sup> and the

383. See, e.g., *Senate Blocks Privacy Project*, N.Y. TIMES, Jan. 24, 2003, at A3 (reporting U.S. Senate vote against Pentagon project to search for terrorists by scanning information in Internet mail and, inter alia, databases of health companies).

384. See generally Nicolas P. Terry, *Privacy and the Health Information Domain: Properties, Models and Unintended Results*, 10 EUR. J. HEALTH L. 223, 223-27 (2003).

385. Privacy Standards (Privacy of Individually Identifiable Health Information or PIHI), Final Rule, 67 Fed. Reg. 53182 (Aug. 14, 2002) (to be codified at 45 C.F.R. pts. 160, 164).

386. Security Standards Final Rule, 68 Fed. Reg. 8334 (Feb. 20, 2003) (to be codified at 45 C.F.R. pts. 160, 162, 164).

387. See *supra* note 207.

388. See generally ANGELA CHOY ET AL., HEALTH PRIVACY PROJECT, EXPOSED ONLINE: WHY THE NEW FEDERAL HEALTH PRIVACY REGULATION DOESN'T OFFER MUCH PROTECTION TO INTERNET USERS (2001), [http://www.healthprivacy.org/usr\\_doc/PIP\\_HPP\\_HealthPriv\\_report.pdf](http://www.healthprivacy.org/usr_doc/PIP_HPP_HealthPriv_report.pdf); Press Release, Pew Internet & American Life Project, Federal Health Privacy Regulation Does Not Cover Most Internet Medical Searches, Services, or Purchases (Nov. 19, 2001), <http://www.pewinternet.org/releases/release.asp?id=33>.

389. The limited definition of "covered entity" in the federal regulations is one example. 45 C.F.R. § 160.103 (1982).

390. See, e.g., CAL. CIV. CODE § 56.10 (1982); see also UNIFORM HEALTH CARE INFORMATION

federal rules do *not* preempt more rigorous state patient privacy protections.

Patients who go online for medical care or prescriptions are poorly served by PIHI or PIHI-like<sup>391</sup> regulations. Such regulations are usually described as protecting patient *privacy*. In fact, it is more accurate to describe them as disclosure-centric rules that protect patient *confidentiality*. Confidentiality places limits on disclosure, while privacy, much like anonymity,<sup>392</sup> is functionally an antecedent to confidentiality, limiting data collection. Federal and state “privacy” rules generally fail to protect against the collection of patient data or frustrate its collection with anonymity rights.<sup>393</sup> True health privacy protection is, in most U.S. jurisdictions, limited to older common law rules that are limited and lack generalized robustness. They tend to be nominate and discrete rules rather than applications of any general privacy principle.<sup>394</sup>

Amongst those who provide online care, traditional telemedicine practitioners are likely to be PIHI-covered entities.<sup>395</sup> As a result they will be over-regulated when they also fall under revised telemedicine statutes that require specific disclosures or protections relating to privacy and security.<sup>396</sup> In contrast, non-traditional providers, such as those engaged in Internet prescribing and dispensing (larger e-pharmacies and PBMs aside), generally are not covered by disclosure-centric regulation. Thus, they tend to be under-regulated. Privacy regulation affecting this latter group generally will be limited to scenarios where the business has published a privacy policy that it then breaches.<sup>397</sup>

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ACT, PROPOSED REVISIONS (2000), <http://www.law.upenn.edu/bll/ulc/uhcia/hci0600.pdf>.

391. Even in states with relatively strong privacy protection. *See, e.g.*, CAL. CIV. CODE § 56-56.37 (1982); MONT. CODE ANN. §§ 50-16-501 to 50-6-504 (2003); R.I. GEN. LAWS § 5-37-22 (2004); WASH. REV. CODE §§ 70.02.005 to 70.02.904 (2002); WIS. STAT. §§ 146.83, 610.70(3) (1997).

392. Anonymity enhances privacy by frustrating the collection of personal identifiers.

393. *See* Terry, *supra* note 384, at 223-37.

394. RESTATEMENT (SECOND) OF TORTS § 652A(2); *see, e.g.*, Knight v. Penobscot Bay Med. Ctr., 420 A.2d 915 (Me. 1980) (involving doctor taking photographs of dying cancer patient); Berthiaume v. Pratt, 365 A.2d 792 (Me. 1976) (finding that where nurse’s husband watched plaintiff’s wife’s delivery the claim failed on the facts because there was no proof of intentional intrusion).

395. *See supra* note 389 and accompanying text.

396. *See supra* notes 85-86 and accompanying text.

397. *See, e.g.*, Press Release, Fed. Trade Comm’n, *supra* note 353.

## 2. *The Error/Risk Externality*

Patient utilization and enthusiasm for all aspects of online care continue to increase,<sup>398</sup> despite considerable skepticism from the medical profession as to its quality.<sup>399</sup> Indeed, there are signs that patients who search for advice are cognizant of declining quality,<sup>400</sup> although not particularly troubled by that phenomenon.<sup>401</sup> Clearly, however, patients using online care (e.g., advice sites, email contact with physicians, telemedicine, telehealth, or Internet prescribing and fulfillment) are internalizing certain costs (risks) that are either not present or not as high in traditional healthcare delivery.

In the Internet prescribing and fulfillment domains, these enhanced risks include: 1) the identity and qualifications of the prescriber; 2) the choice of drug; 3) the quality of the drug; 4) follow-up treatment or advice; and 5) indeterminacy of recourse.<sup>402</sup> Internet users likely have some awareness of the first of these risks, while those who opt for Internet prescribing or dispensing services are likely to have already made the drug choice. Non-traditional channels clearly do not offer the persistence of a physician-patient or pharmacist-patient relationship that tends to guarantee quality care. In the event of a problem with the drug, whether because of fraud or error, recourse against an online provider will be problematic.

It is extremely difficult to map out a constitutionally acceptable legal strategy to control web content or advice<sup>403</sup> in the absence of obviously dangerous activities, products, or services.<sup>404</sup> Not surprisingly, therefore, considerable faith is placed in technological or self-regulatory solutions in an attempt to reduce patient-incurred risks.

Many of the novel risks introduced by online care involve information

398. See *supra* note 352.

399. See *supra* note 351 and accompanying text.

400. See *supra* note 352.

401. *Online Medical Advice Expands: Some Data Shaky, but Public Unfazed*, MIAMI HERALD, Jan. 05, 2003.

402. See generally C. Anderson, *A Call for Internet Pharmacies To Comply with Quality Standards*, 12 QUALITY SAFETY HEALTH CARE 86 (2003) (discussing poor quality of consumer information on Internet prescribing and dispensing sites (particularly drug interaction information), out-of-date stock, and substitution).

403. See generally Nicolas P. Terry, *Cyber-Malpractice: Legal Exposure for Cybermedicine*, 25 AM. J.L. & MED. 327 (1999); Nicolas P. Terry, *A Transatlantic Perspective on Regulating Health Information*, 324 BRIT. MED. J. 602 (2002).

404. See *supra* notes 235-236 and accompanying text.

costs incurred by patients. These include the quality-related risks such as the identity and qualifications of the prescriber as discussed above. Specifically, the cost-quality-access formula has different values in the online context. The conventional health law tool for dealing with information asymmetry or choice is informed consent. Case law has not yet developed in this area, but as already noted,<sup>405</sup> some state legislatures have introduced enhanced consent provisions for some aspects of online care that may affect prescribing or dispensing. These provisions, however, tend to focus on warning of risks associated with Internet prescribing and dispensing, or on the mechanics of telemedical services, such as security, privacy, or other unarticulated "technology" risks that seem less conducive to improving patient choice.

#### *D. Over-regulation*

There is no doubt that states, encouraged by federal regulators and professional organizations, are attacking Internet prescribing and dispensing with reformulated regulatory standards and renewed enforcement vigor. Across the country, medical boards, assisted by compliant attorneys general, are seeking injunctive relief against physicians and pharmacists who stray into their states' web space. Some of this regulation and enforcement is prophylactic. States are finding it easier to use licensure regulation than prove the more difficult burdens associated with, say, the *mens rea* component for illegal drug distribution or the elements of consumer fraud.

The state boards and the AMA have articulated two primary objections to Internet prescribing. First, it operates independent of a physician-patient relationship, and second, drugs are prescribed in the absence of a physical examination. These two features are deeply offensive to the medical establishment's view of how healthcare is or should be delivered. That paradigm is centered on an in-person office consultation between an informed professional and compliant patient who are in a long-term relationship. The physician performs a fact-finding inquiry, including a physical examination, that informs the diagnosis and, where appropriate, the writing of a prescription. The patient takes the prescription to a bricks-and-mortar pharmacy or a VIPPS certified e-pharmacy, where an additional layer of error-checking occurs and additional effects and interaction information may be provided.

For some regulators, the absence of a physician-patient relationship or

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405. See *supra* notes 77-83 and accompanying text.



physical examination is little more than code for technophobia or a conflation of normative objections to Internet prescribing with regulatory language that best identifies its practitioners. Both of these traditional indicators, however, have deeper constructs and cannot be lightly dismissed.

The “physician-patient relationship” concept exists in three overlapping domains: ethical, legal, and operational. As an ethical construct, it is the foundation of competence, respect, and confidence.<sup>406</sup> In the legal domain, the existence of a “physician-patient relationship” establishes the contractual responsibilities of the parties (such as service and payment) and is the touchstone for legal duty, signifying that the physician must internalize some of the patient’s treatment risks.<sup>407</sup>

In the Internet prescribing debate, the “physician-patient relationship” is primarily used in its third operational sense where it is coterminous with “continuity of care.” Continuity of care has several components; the most important of which are access to the patient’s existing record (and the correlate responsibility of adding to that record to minimize fragmentation of patient data) and availability of follow-up care. Continuity also lowers transaction costs, such as positively identifying the patient and matching her to any ongoing treatment plan (replete with information about possible drug interactions), while its sense of longevity may translate into a more holistic therapeutic plan, rather than purely pharmaceutical treatment. In contrast to this “continuity” model, Internet prescribing is centered on an opportunistic physician-patient relationship, defined by a single pharmaceutical transaction.

The concept of “physical examination” is also multi-layered. It too reduces transactions costs by facilitating the positive identification of the patient and makes it more likely that the white-coated person in the office is actually a licensed physician. Therapeutically, a physical examination may add to the quality of the diagnosis, and a face-to-face interaction may

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406. See, e.g., Am. Med. Ass’n, *Principles of Medical Ethics*, June 2001, at <http://www.ama-assn.org/ama/pub/category/2512.html> (last visited Apr. 17, 2004).

407. See, e.g., *Sterling v. Johns Hopkins Hosp.*, 802 A.2d 440 (Md. 2002) (holding that a hospital that accepted the transfer of a patient without having any direct contact with that patient and whose doctor engaged in discussion with patient’s doctor over transport options was entitled to summary judgment because its doctor did not have a physician-patient relationship with the patient, who was still under the care of her doctor); *Kruger ex rel. Estate of Kruger v. Jennings*, 2002 WL 344268 (Mich. Ct. App. 2002) (holding that an on-call surgeon who offered advice to the physicians working with a patient could be held to have been in physician-patient relationship because he actively participated in the course of treatment), *superseded by* *Kruger v. Jennings*, 2002 WL 652098 (Mich. Ct. App. 2002).

provide the physician visual clues as to the patient's health and, perhaps, truthfulness in answering questions. Again, there is a legal and regulatory subtext. An examination places the patient-physician interaction in physical space, facilitating regulatory scrutiny while making it more likely that the provider is a bricks-and-mortar provider covered by modern privacy laws.

Whether or not medical boards articulate or fully explain these objections to Internet prescribing, they know them when they see them; the primary identifier for regulators is substitution of an online questionnaire for aspects of the traditional paradigm.

### *1. Questionnaire Prescribing*

There are no easy answers to the inquiry into exactly what is occurring in the online prescribing interaction between patients and Internet prescribers. It is self-evident that there are websites supplying U.S. patients with prescription drugs without even the most rudimentary safeguards. In such cases, the only requirement for consumer access to controlled substances or prescription drugs is a credit card. The drugs may or may not be fakes; they may or may not be delivered or delivered in good condition; and obtaining the consumer's credit card information may well be the first step in an identity theft fraud. For some regulators, the existence of this unquantified criminal activity may itself be justification for closing down *all* Internet prescribing and dispensing.

From the perspective of regulators, the Internet prescribing case is well-represented by *United States v. Nelson*, in which the United States Court of Appeals for the Tenth Circuit upheld a physician's conviction for conspiracy to prescribe controlled substances and money laundering.<sup>408</sup> Nelson and his co-conspirators created NationPharmacy.com, which distributed controlled substances, particularly the Schedule II painkiller Hydrocodone.<sup>409</sup> Nelson periodically visited the pharmacy and signed thousands of "questionnaire" prescriptions at a time.<sup>410</sup>

We know little about the slightly less seamy side of Internet prescribing and dispensing. This is because state medical boards tend to work off an absolutist model and the physicians and pharmacies they prosecute have little to gain from fighting the charges. It makes more sense for culprits to

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408. 72 Fed. Appx. 837 (10th Cir. 2003).

409. See U.S. Drug Enforcement Admin., *Hydrocodone*, at <http://www.usdoj.gov/dea/concern/hydrocodone.html> (last visited Apr. 17, 2004).

410. 72 Fed. Appx. at 839.

agree to a consent decree, and then register or spoof a new domain name or move on to states with less committed or effective enforcement. An exception is the Kansas case, *State ex rel. Stovall v. Confirmed.com, L.L.C.*<sup>411</sup> The first Internet prescribing case to reach a state high court, *Stovall* involved a successful “sting” operation that caught out-of-state prescribers and dispensers delivering prescription drugs. *Stovall* suggests, however, that there are grey areas of Internet prescribing and dispensing and, further, that the courts may not always share the black-and-white antipathy of state boards and prosecutors.

An investigator and the supervised minor son of another investigator purchased Viagra<sup>412</sup> from a website operated by an out-of-state physician; neither the physician nor the pharmacy were licensed to practice in Kansas. The site appeared to be quite robust. It had the usual e-commerce functions, a liability waiver, warnings about the drug, recommended dosage, links to information on the drug manufacturer’s site, and required the patient to represent that he had received a recent physical. The female investigator and the minor filled out the diagnostic questionnaire. The minor did not fill out all the diagnosis questions on the form, though he did give symptoms suggesting erectile dysfunction. The minor’s order was filled but the female investigator’s request for Viagra was initially denied. An employee of the physician-pharmacy contacted the agent and informed her that Viagra could not be supplied to a female. The drug was supplied when the agent resubmitted the order and questionnaire under a false, male name.

Predictably, the trial court granted the state’s application to enjoin the defendants from dispensing medication or practicing medicine in Kansas.<sup>413</sup> The issue was whether such conduct breached the state’s consumer protection act<sup>414</sup> and enabled the prosecutors to recover attorney fees, investigative fees, and penalties. The trial court held that the consumer protection act was not breached, noting:

[T]here was no actual harm done to anyone. Nothing was misrepresented. All drugs furnished were authentic. The pharmacy expert testified that if the waivers in the orders signed by the investigators were true, more would have been understood by them than ‘regular’

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411. 38 P.3d 707 (Kan. 2002).

412. A companion case, *State ex rel. Stovall v. DVM Enters.*, 62 P.3d 653 (Kan. 2003), dealt with a similar sting involving controlled substances, but the court came to the same basic conclusion.

413. 38 P.3d at 709.

414. KAN. STAT. ANN. §§ 50-636, 59-623, 59-627 (2004).

doctors and druggists typically advise their patients or customers. . . .<sup>415</sup>

The Supreme Court of Kansas affirmed, refusing to hold that a seventy-five dollar consultation fee, prescribing without a physical examination, or supplying the drug to a minor constituted consumer fraud.<sup>416</sup> Neither the trial court nor the Supreme Court approved of the conduct of the defendant,<sup>417</sup> but the courts were also clearly not pleased by the agents' false representations in conducting the sting. Notably, the Supreme Court made a point of referring to the state's pharmacy expert's statement that "had the purchasers in fact read the manufacturer information about Viagra, they would know more information than [the expert] provides his own customers. *He also admitted that the questions asked on the computerized consultation form were more in depth than those he poses to individuals who have been prescribed Viagra.*"<sup>418</sup>

Of course, not all questionnaires are created equal. For example, some are rudimentary and merely tacked onto the end of order forms, showing contempt for the medical process of prescribing. Some electronic forms have their defaults set in a more dangerous fashion. For example, if medical history questions are pre-answered as "none," the patient has to affirmatively overrule the default.<sup>419</sup> The snapshot of Internet prescribing and dispensing supplied by *Stovall* is not necessarily representative. However, what we learn is that licensed professionals do staff at least some of these sites and that not all prescription requests are automatically filled.

## 2. A Suspect Paradigm: The Realities of Modern Bricks-and-Mortar Medicine

A major component of the "bad medicine" premise behind the targeting of Internet prescribing is that it compares so unfavorably with the bricks-and-mortar paradigm. As succinctly addressed by the physician's attorney in the Kansas Viagra case, "Doctors who prescribe in the office don't examine your equipment, so what is the real medical issue that is not being addressed?"<sup>420</sup> In fact, the prescribing paradigm relied on by state

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415. 38 P.3d at 710 (describing lower court findings).

416. Cf. ARK. CODE ANN. § 17-92-1007 (Michie 2002) (deeming breach of the Arkansas Internet Prescription Consumer Protection Act to constitute unconscionable conduct under the state consumer protection statute); see also *id.* § 4-88-107.

417. The court quoted the trial judge's statement that "these people ought to be defrocked as medical practitioners, as pharmaceutical practitioners." 38 P.3d at 715.

418. 38 P.3d at 714 (emphasis added).

419. Siwolop, *supra* note 88.

420. *Web Prescriptions Thrive Despite Sting*, WASH. TIMES, Mar. 5, 2002, at A1 (quoting James

regulators bears only passing resemblance to the realities of modern healthcare delivery.

The cradle-to-grave physician-patient relationship has long since disappeared. Continuity of care may be a valid goal, but not one that seems able to co-exist with managed care; it is now employers and HMOs that decide whether the patient has the same physician from one year to the next. Continuity of care is also hard to detect in treatment provided by fee per visit walk-in centers,<sup>421</sup> the pejoratively labeled “doc-in-a-box” or “mall medicine.” Here, the AMA has been consistent, approaching these new forms of transient relationships with the same type of concern displayed toward online care, primarily objecting to any misleading use of the term “emergency” in the branding or marketing of these walk-in centers.<sup>422</sup>

The “physician” component of the paradigm is also overstated; collaborative, protocol, or formulary prescribing by nurse practitioners is now widespread,<sup>423</sup> and New Mexico has become the first jurisdiction to permit prescribing by psychologists, independently within a formulary and collaboratively in other cases.<sup>424</sup> The paradigm’s reference to a single “physician” is also inaccurate; we now recognize the growth and importance of “shared care,”<sup>425</sup> referring either to more than one physician taking care of a patient or to the growing role and responsibilities of the patient herself in sharing her care with her physician.<sup>426</sup> Research suggests that this is the context for the use of Internet-sourced medical information by patients, not as a substitute for traditional physician-patient relationships, but as a way of increasing their knowledge and asserting

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R. Jarrow).

421. See Milt Freudenheim, *Shopping Mall Medicine*, N.Y. TIMES (MAGAZINE), Dec. 5, 1982, at 6-146.

422. See AM. MED. ASS’N, FREESTANDING EMERGENCY MEDICAL CARE POLICY (1993), [http://www.ama-assn.org/apps/pf\\_new/pf\\_online?f\\_n=browse&doc=policyfiles/HnE/H-130.990.HTM](http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-130.990.HTM) (last visited May 1, 2004).

423. See, e.g., ALA. CODE § 34-21-81 to -87 (1975).

424. N.M. STAT. ANN. § 61-9-17.2 (Michie 2004). This statute has been repealed, effective July 1, 2010.

425. See Steve O’Dell & Jim Hansen, *The Next-Generation Health Plan: Not If, but When and How*, HEALTHPLAN, Mar./Apr. 2003, at [http://www.aahp.org/Content/NavigationMenu/Inside\\_AAHP/Healthplan\\_Magazine/March\\_April\\_2003\\_Essentials\\_The\\_Next-Generation\\_Health\\_Plan\\_\\_Not\\_If\\_but\\_When\\_and\\_How.htm](http://www.aahp.org/Content/NavigationMenu/Inside_AAHP/Healthplan_Magazine/March_April_2003_Essentials_The_Next-Generation_Health_Plan__Not_If_but_When_and_How.htm).

426. David Brushwood puts a normative and questioning spin on this sharing of care between patient and medical professional. Brushwood, *supra* note 268, at 96-97.

their autonomy within increasingly reticulated relationships.<sup>427</sup>

We also do not spend much time in the physical presence of our physicians. Routinely, we contact them by phone, poorly describe our symptoms, and expect a prescription to be phoned into a pharmacy. Such a practice is viewed as permissible because there is an existing physician-patient relationship, and the physician has access to some part of our medical record. The prescribing, however, is no less rote than we see in online interactions.

"Traditional" office visits are seldom more robust, with the average primary care visit now lasting approximately fifteen minutes.<sup>428</sup> Patient access to pharmaceutical information, particularly DTC advertising, means that the conversation is as likely to start with a patient's request for a specific drug rather than a physician inquiry as to symptoms.<sup>429</sup> Not to mention the way that managed care compresses the dialogue space and leaves little room for extensive interaction. Many of today's office visits are seldom more didactic than a completed Internet questionnaire. The most compelling argument in favor of the depleted paradigm may be that a bricks-and-mortar physician is less likely to have a financial interest in the dispensing part of the business than her online counterpart.<sup>430</sup> The traditional paradigm is not just collapsing in the medical domain; our regulatory systems themselves recognize that things are not as they once were.<sup>431</sup>

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427. See FOX & FALLOWS, *supra* note 54, at 15-16.

428. D. Mechanic et al., *Are Patients' Office Visits with Physicians Getting Shorter?*, 344 NEW ENG. J. MED. 198 (2001).

429. See generally Harris Interactive, *The Impact of Direct-to-Consumer Advertising of Prescription Drugs on Consumer Behavior, Diagnosis and Treatment*, HEALTH CARE NEWS, June 23, 2003,

[http://www.harrisinteractive.com/news/newsletters/healthnews/HI\\_HealthCareNews2003Vol3\\_Iss11.pdf](http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2003Vol3_Iss11.pdf) (finding that seventy-two percent of office visits initiated by a patient after DTC exposure led to a prescription being written, and forty-three percent of times for the specific advertised drug).

430. This results in no small part because of prevailing fraud and abuse laws. See *infra* note 478.

431. See, e.g., ALA. ADMIN. CODE § 540-X-9-.11(2) ("Prescribing for a patient whom the physician has not personally examined may be suitable under certain circumstances. These may include, but not be limited to, admission orders for a patient newly admitted to a healthcare facility, prescribing for a patient of another physician for whom the prescriber is taking call, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment."); N.D. CENT. CODE § 43-15-31.3 (2001) (permitting oral/telephone transmission of prescription information from doctors to pharmacists).

### 3. Imperiled Next Generation Models

Some medical boards clearly equate questionnaire prescribing with the most undesirable forms of Internet prescribing. For these regulators, the questionnaire is an artifice, an attempt to fool regulators and patients into believing that individuated diagnosis precedes the shipment of dangerous drugs across state borders. Therefore, for the boards to crack down on questionnaire prescribing is to move against the worst excesses of the trade, cynical pill-mills that jurisdiction hop to avoid health and safety scrutiny. The analysis gets more interesting, however, when we examine how a state board reacts to questionnaire prescribing integrated into an e-health model that seems to lack some or all of these undesirable indicia, such as “online doc-in-a-box,”<sup>432</sup> e-businesses,<sup>433</sup> and, potentially, “second opinion” sites.

MyDoc.com<sup>434</sup> was first launched in Indiana and then briefly expanded to Illinois in April 2002.<sup>435</sup> Originally a division of Swiss-based Roche diagnostics,<sup>436</sup> it was sold to U.S. Health Services in 2003, a unit of Standard Management Corp., which markets pharmaceutical products and services to consumers.<sup>437</sup> MyDoc.com’s business model was somewhat unique in that it was owned by a well-known healthcare company and charged on a pay as you go, annual subscription, or employer-paid subscription basis.<sup>438</sup> It also

432. If patients are not already asking the question, “What’s your email address, doctor?,” they will be soon. Dorothy L. Pennachoi, *What’s Your Email Address, Doctor?*, 80 MED. ECON. 66 (2003).

433. See, e.g., VirtualMedicalGroup, at <http://www.virtualmedicalgroup.com/> (last visited Apr. 17, 2004). It promises:

You are in the right place if you want to experience quality health care. VirtualMedicalGroup Board Certified physicians who are licensed in your home state, treat minor, non-emergent medical conditions in the privacy of your own home or office. We have been in business for over three years - longer than anyone on the web - as a result of our focus on patient confidentiality, convenience and quality care.

*Id.*

434. The website for MyDoc.Com (formerly at <http://www.mydoc.com>) is no longer accessible.

435. Mave Davis, *Internet Doctors Make a Move to Illinois*, CHI. TRIB., May 5, 2002, at 6A.

436. *Online Firms Tout Cyber Physicians; But Some Docs Question Virtual Visits*, CRAIN’S CHI. BUS., Aug. 5, 2002, at SR11; see *supra* note 421 and accompanying text (discussing of doc-in-box medicine).

437. *Roche Diagnostics Unloads MyDoc.com; U.S. Health Services Corp. Buys Internet Doctor Service and Plans To Keep It Operating*, INDIANAPOLIS STAR, June 13, 2003 at 1C.

438. MyDoc.Com (on file with author).

had features that distanced it from the typical Internet pill-mill. First, it treated or prescribed only to residents of Indiana. Second, it employed physicians who were board-certified in Indiana and, unlike the “pill-mills,” their identities were disclosed on the website.<sup>439</sup> Third, it refused to prescribe controlled substances or lifestyle drugs<sup>440</sup> and referred complex inquiries to specialists or the patient’s existing physician. Fourth, the site featured “next generation” questionnaire prescribing that is better described as questionnaire triaging. Once a patient completed a questionnaire, it was analyzed by an expert system that could then pose additional online questions to the patient. The attending physician could then follow-up in real-time to acquire further information. Finally, any prescribed drugs were not supplied directly by the site; a prescription was communicated to a pharmacy chosen by the patient.<sup>441</sup>

While MyDoc.com prospered in Indiana—at least briefly,<sup>442</sup> when it attempted to commence business in Illinois, the State Department of Professional Regulation issued a cease-and-desist order in October 2002 on the basis of “unlicensed practice of medicine including, but not limited to, treating patients over the Internet and prescribing medication to patients over the Internet without the benefit of performing a physical examination on the patient.”<sup>443</sup> The company complied with the order.<sup>444</sup> The medical establishment commended Illinois’s action; the AMA stated that it “applauds the efforts of state authorities to aggressively police Web prescribing sites that bypass medical safeguards with disclaimers that suggest a physical examination or review of reliable medical history are irrelevant to the safety of the patient.”<sup>445</sup>

Even more benign than virtual walk-in centers are web-based “second opinion” services. In this model, a patient makes web contact with an online medical consultancy, many of which are affiliated with large teaching or research hospitals such as the Cleveland Clinic,<sup>446</sup> and

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439. *Id.*

440. *Id.*

441. Davis, *supra* note 435.

442. Jeff Swiatek, *Illinois Sidelines MyDoc.com Service*, INDIANAPOLIS STAR, Oct. 31, 2002, at 1C.

443. Ill. Dep’t of Prof’l Regulation, Disciplinary Report for October 2002, [http://www.ildpr.com/news/discpln/0210\\_dis.pdf](http://www.ildpr.com/news/discpln/0210_dis.pdf) (last visited May 17, 2004).

444. See Ann Carrns, *Illinois Orders Indiana Web Site To Stop Offering Medical Service*, WALL ST. J., Oct. 30, 2002, at D4.

445. Tyler Chin, *Firm Treating Strangers by Web Shut Out by Illinois*, AMNews, Nov. 4, 2002.

446. See E-Cleveland Clinic, at <http://www.eclevelandclinic.com> (last visited Apr. 17, 2004); see also Virtual Medical Group, at <http://www.virtualmedicalgroup.com/> (last visited



authorizes access to her medical record and a credit card charge ranging from \$500 to several times that amount.<sup>447</sup> A consultant reviews the record and emails a diagnosis back to the patient. One such system has published a retrospective review demonstrating improved response times compared to traditional second-opinion references, but only a small number of dissenting diagnoses.<sup>448</sup>

Such second opinion sites have opportunistic characteristics in that a prior relationship with the consulting physician is unlikely. Also, they tend to feature record review rather than a physical examination. However, such services tend not to get involved in prescribing, and their record review process furthers continuity of care by involving or at least copying their opinions to the patient's existing physician.<sup>449</sup> It has also been argued that physical contact with the patient is less important in second opinion consultation cases, where most of the analysis flows from review of blood work, scans, and pathology tests and primarily concerns treatment options rather than core diagnoses.<sup>450</sup>

## VI. RETHINKING THE REGULATION OF INTERNET PRESCRIBING AND DISPENSING

This Article does not argue for anything less than a rigorous drug approval system, a licensure system for physicians and pharmacists, and robust enforcement of gatekeeper and quality standards. It accepts with only limited reservations (such as cases of protectionist discrimination or where there are less restrictive means) that it is entirely legitimate for states to enforce their licensure systems and professional standards in a way that has an impact on Internet prescribers and dispensers both inside and outside their borders.

Rather, this Article argues that the current regulatory matrix is inefficient, incoherent, and imprecise in its targeting. It is inefficient because the general deterrence model that the state regulators use (stinging pill-mills where they can find them in the vain hope that others

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Apr. 17, 2004); MDExpert.com, at <http://www.mdexpert.com> (last visited Apr. 17, 2004).

447. MDExpert.com quotes fees ranging from \$2800 to \$3200 depending on complexity. MDExpert.com, *Frequently Asked Questions about MEDExpert*, at [www.mdexpert.com](http://www.mdexpert.com) (last visited Apr. 17, 2004).

448. Iris Kedar et al., *Internet Based Consultations To Transfer Knowledge for Patients Requiring Specialised Care: Retrospective Case Review*, 326 BRIT. MED. J. 696 (2003).

449. See Daniel Costello, *Virtual Second Opinions*, L.A. TIMES, Dec. 30, 2002, at F1.

450. See Tara Parker-Pope, *Virtual Second Opinions: When the Web Can Be Better than Seeing a Local Doc*, WALL ST. J., Aug. 12, 2003, at D1.

will be deterred) does not map well to a technologically sophisticated underground online industry that continually changes its real space and cyberspace identities and locations. It is an enforcement model that is ultimately doomed because the demand side is robust and unconvinced that the regulators have a valid moral imperative. The vast majority of patients want less expensive<sup>451</sup> and more responsive services; increasingly, they want to buy their medical services and pharmaceuticals online and are unconvinced that traditional distribution channels are any better attuned to their needs.

The current model is incoherent due to the over-complexity of the regulatory matrix. State, federal, and self-regulatory bodies administer an overlapping series of systems that are united in conservatism and tunnel vision. At the extremes, they exhibit parochialism and even technophobia. Their models are imprecise because they are not derived from forward-looking national or local health information infrastructure planning. As such, they derive their mandates from an outdated model of healthcare delivery and not from a conceptual model that distinguishes between types of online health interaction that should be encouraged rather than chilled or deterred.<sup>452</sup> The model is also operationally flawed. It fails to adequately carve out regulatory approval (or appropriate levels of regulation) for traditional telemedicine, while the blunt tools it uses to identify rogue practitioners (i.e., physician-patient relationships and physical examinations) poorly serve the regulators and regulated alike in the face of next generation delivery models.

The United States is moving inextricably towards a more efficient national healthcare infrastructure that is firmly rooted in technologically-mediated exchanges.<sup>453</sup> The system being built is not only transactional,

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451. Earlier I discussed today's online market for lifestyle drugs—including patients who may be willing to pay more for the convenience of purchasing such drugs in a covert fashion over the internet. *See supra* paragraph preceding note 101. While these patients have been some of the first to purchase drugs over the Internet, they represent a subset of the overall patient population; going forward an increasing number of patients will consider purchasing their medications online, and this mainstream consumer population will be motivated in significant part by potential cost savings.

452. For discussion of chilling in this context, see PUBLIC WORKSHOP, *supra* note 313, at 652.

453. The National Committee on Vital and Health Statistics (NCVHS), *see* U.S. Dep't of Health & Human Servs., Nat'l Comm. on Vital and Health Statistics, at <http://ncvhs.hhs.gov/> (last visited Apr. 17, 2004), is responsible for the National Health Information Infrastructure, Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 263, 110 Stat. 1988 (1996). The broad goals of NCVHS are to deliver

requiring correlate security and privacy protections, but will integrate the Institute of Medicine's (IOM) technology-based solutions to medical and medication error.<sup>454</sup> Moving forward requires not only persuading regulators that unlawful cross-border Viagra peddling is distinguishable from the "war on drugs" but also that it is a transitional phenomenon, an experiment in online care that is filling the vacuum created by skepticism regarding technologically mediated care. Improvements in the regulatory matrix, therefore, will necessitate not only far more circumspection about practice models that require policing or deterring, but also affirmative steps to encourage innovation by lawful players.

#### *A. Improving the Prescribing Regulatory Model*

There is little doubt that e-prescribing<sup>455</sup> will become the default interface for prescribing in secondary and tertiary care environments. While supervised by physicians or nurse-practitioners and integrated into sophisticated risk-management systems, prescriptions will increasingly be the product of expert systems rather than traditional physician-patient interactions. Online prescribing will take on a similar role in primary care environments.<sup>456</sup> The current regulatory atmosphere is chilling the development of responsible open or public systems; instead, innovative models are developing more slowly as adjuncts to traditional care models within existing health plans<sup>457</sup> or in proprietary systems like Medem.<sup>458</sup>

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information to consumers, patients, and professionals that is to be used to make informed decisions about health and health care. U.S. DEP'T OF HEALTH & HUMAN SERVS., NAT'L COMM. ON VITAL AND HEALTH STATISTICS, NHII WORKGROUP ON THE NAT'L HEALTH INFO. INFRASTRUCTURE, INTERIM REPORT, TOWARD A NATIONAL HEALTH INFORMATION INFRASTRUCTURE (2000), at <http://ncvhs.hhs.gov/NHII2kReport.htm>. States are making their own modest contributions by, for example, permitting electronically created and transmitted prescriptions. See *supra* note 17 (discussing such a provision in Massachusetts law).

454. See, e.g., COMM. ON QUALITY OF HEALTH CARE IN AMERICA, *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* (2001) [hereinafter *CROSSING THE QUALITY CHASM*].

455. For a definition of e-prescribing, see *supra* note 17.

456. See, e.g., *Bye-Bye, Paper Rx? E-Prescribing Could Boost Convenience, Safety—Given Time*, WASH. POST, July 1, 2003, at HE01 (using term "e-prescribing" to describe Internet delivery of prescriptions from HMOs and doctors' offices to pharmacies).

457. See, e.g., *Virtual Doctors on the Horizon in Seattle*, 354 LANCET 9182 (1999) (reporting a Virtual Clinic closed system provided by a Seattle hospital to Microsoft employees).

458. The Medem Network: Connecting Physicians and Patients Online, at <http://www.medem.com> (last visited May 15, 2004).

Medem was founded in 1999 by the AMA and several other professional associations and is a proprietary, for-profit physician-patient communications network that enables physicians to use secure email and messaging with existing patients.<sup>459</sup> To an extent, Medem is online healthcare's AOL, a halfway house for physicians on the way to e-health.<sup>460</sup>

States will be increasingly forced to recognize the benefits of online care<sup>461</sup> and its importance to the future of safe and efficient healthcare delivery.<sup>462</sup> The challenge, therefore, is to design a regulatory system for Internet prescribing and dispensing that will not chill existing, responsible models of online practice (i.e., traditional telemedicine and home telehealth) or impede the development of millennial delivery models (i.e., those for prescribing and dispensing that are part of our e-health future).

The classic answer to this question is a national licensure system for physicians, but this is an unlikely short or medium term option. States are no more of a mind to forego their licensing powers than the federal government is to expand its regulatory purview.<sup>463</sup> Even if the political and policy climate were more favorably disposed toward such a move, federal licensure would not necessarily solve the Internet prescribing issue. Although a national system would reduce the chilling effect that comes from questions as to whether multiple licenses are required and

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459. See Press Release, Medem, Physician Associations Announce Health Care Information and Communications Web Site (Oct. 28, 1999), [http://www.medem.com/press/press\\_medeminthenews\\_detail.cfm?ExtranetPressNewsKey=1](http://www.medem.com/press/press_medeminthenews_detail.cfm?ExtranetPressNewsKey=1) (last visited May 15, 2004).

460. Cf. James Surowiecki, *The Future of AOL: Spin Off and Prosper*, WIRED (October 2002) (suggesting AOL could improve its financial position through innovation if Time Warner would spin off the division).

461. See, e.g., ALA. CODE § 34-24-500 (2000) ("The Legislature hereby finds and declares that, because of technological advances and changing practice patterns, the practice of medicine . . . is occurring with increasing frequency across state lines and that certain technological advances in the practice of medicine . . . are in the public interest . . ."; see also HealthyOregon, at <http://www.healthyoregon.org/> (last visited Apr. 17, 2004).

462. See CROSSING THE QUALITY CHASM, *supra* note 454, at 168-69 (listing "Health-Related Applications for the Internet").

463. Cf. Medicare Telehealth Validation Act of 2002, S. 2750, 107th Cong. § 2(c)(1) ("[T]he Secretary . . . in consultation with representatives of States, physicians, healthcare practitioners, and patient advocates, encourage and facilitate the adoption of State provisions allowing for multi-state practitioner licensure across State lines."). The same language is adopted in Medicare Telehealth Validation Act of 2003, H.R. 1940, 108th Cong. § 2(c)(1), and the Medicare Prescription Drug Benefit Bill, S. 1, 108th Cong. § 450H(b)(1) (2003).

inconsistent regulation, federal licensure by itself does not go to the root issues of opportunistic relationships and suspect care.

Short of national licensure, however, the states can still build a better mousetrap. They must begin by recognizing that, today, the case for regulatory heterogeneity and the disfavoring of technologically-mediated care is quite weak. State regulators can work cooperatively with one another—witness the work of the Federation of State Medical Boards<sup>464</sup>—and develop a uniform licensure and practice code. This code should adopt a standardized test for the “practice of medicine” and set common standards and limitations for online interactions.

The most immediate standardization must come from closed (as contrasted to public Internet) systems, telemedicine, and telehealth applications such as home monitoring. The closed nature of these systems immunizes them from the problems associated with opportunistic interactions, and they are far less likely to involve prescribing. The old telemedicine consult model may no longer be accurate, and nationally consistent standards of consent and record-keeping may be appropriate. There is no reason, however, to chill these practices with inconsistent state regulations or standards that discriminate between chosen technologies and those that feature interstate, as opposed to intrastate, interactions. As with other proposals discussed herein, regulatory scrutiny is required not only for the direct cross-border issues but also for more indirect changes designed to protect consumers engaging in online medicine and promote confidence in the systems that develop. For example, privacy protections for online patients not obviously covered by the PIHI regulations are required. It is unlikely that the United States will move anytime soon to a full collection-centric privacy model. However, both federal<sup>465</sup> and state<sup>466</sup> legislators have considered bills that would remove some of the voluntarism presently found in the publication of privacy policies, for example, by mandating compliance with published privacy policies and disclosure of breaches of privacy or security.

Open (or public Internet) systems are more problematic given the

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464. *See, e.g.*, FED’N OF STATE MED. BDS., REPORT OF THE SPECIAL COMMITTEE ON PROFESSIONAL CONDUCT AND ETHICS (2000), [http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/internet\\_use\\_guidelines.htm](http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/internet_use_guidelines.htm); FED’N OF STATE MED. BDS., REPORT OF THE AD HOC COMMITTEE ON TELEMEDICINE (1996), <http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/telemed.htm>.

465. *See, e.g.*, Online Personal Privacy Act of 2002, S. 2201, 107th Cong. (2002).

466. *See, e.g.*, California Online Privacy and Disclosure Act of 2002, A.B. 2297 (Cal. 2002).

potential for opportunistic relationships and sub-standard care. The emerging regulatory touchstones for lawful interaction (an existing physician-patient relationship and physical examination) are too restrictive and chill the development of next generation models. There are less restrictive means to outlaw pill-mills, regulate responsible practice, and encourage innovation. Such standards should be the criteria for a uniform online practice certification.

As argued above, there is little literal magic in the requirement of a "physician-patient relationship." Rather, in this context, regulators are (or should be) concerned about the absence of "continuity of care." Therefore, continuity of care, or rather its deconstructed elements, should be made a requirement for online systems. Rather than demanding an extant relationship (a requirement not imposed on bricks-and-mortar walk-in centers), harmonized state laws should require online providers to establish contact with the patient's existing record and assume the correlate responsibility of adding to that record. Online providers must also show a commitment to continuing or follow-up care.

Similarly, there are less restrictive ways for harmonized state standards to achieve the goals that underlie the requirement of a physical examination. Positive identification of both patient and physician can be achieved using digital certificates.<sup>467</sup> The therapeutic aspects of physical presence can be approximated by establishing protocols for the non-physical interactions, such as the development of model questionnaires which would include questions that allow for cross-checking responses. There should always be a requirement that the online system is only an initial step, a triage, and the physician has to establish an appropriate system for individual follow-up, by phone, email, or messaging. Such standards must factor in the availability and use of "physical," but technologically-mediated, examinations, such as those being incorporated in telehealth appliances in the home or integrated into mobile devices such as cell phones.

As part of the incubation of, and experimentation with, online care, there should be limitations placed on its utilization. Protocols should address the situations when the online interaction must be halted and the patient referred to a bricks-and-mortar provider. Equally, we must move away from a monolithic approach to online care. Some diagnoses and

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467. See, e.g., Steve Gold, *Site Employs Biometrics*, Newsbytes, at <http://www.computeruser.com/newstoday/00/04/18/news6.html> (Apr. 18, 2000) (detailing use of BioNetrix biometrics technology to authenticate the identities of doctors ordering patient prescriptions over the Internet from the online pharmacy).

some prescribing may be more consistent with technologically-mediated care than others. An online practice certificate should be conditioned on specialized training and restricted to developed protocols that place limits on the types of treatment and any resultant prescribing. Such a model can be adapted from that applied to nurse-practitioners. Similarly, online practice and prescribing can be limited by protocol, and prescribing can be further limited to a specific formulary of legend drugs or the exclusion of controlled substances.<sup>468</sup> Current overreaching pharmacy regulations that require the dispenser to be satisfied that prescribing was preceded by a physical examination could be reworked to prohibit the filling of an online prescription for a non-protocol drug or by a certified practitioner (a practitioner having undergone the appropriate training).

### *B. Reforming Online Dispensing*

Such a system of online practice certification and limitation by protocol does not require FDA action. The protocol or formulary prescribing limitations, however, could be encouraged and reinforced if the drug approval process adapted the controlled substances schedule approach<sup>469</sup> to all prescription pharmaceuticals. If sub-categories of ordinary prescription drugs were developed, the FDA and manufacturers could then evolve warning and labeling requirements that would better meet the needs of online prescribing.

Continuing to require multi-state licensing of pharmacies is a much closer case. There is a good argument that we should move away from a paternalistic paradigm and allow patients more choice, including interstate supply.<sup>470</sup> Such a paradigm shift in how we view patient choice in the drug arena is not unheard of. For example, the learned intermediary rule that requires drug warnings to be delivered to physicians rather than patients is riddled with exceptions when robust drug information is or could be delivered directly to patients through package inserts<sup>471</sup> or DTC advertising.<sup>472</sup>

A relaxation of cross-border traffic for pharmaceutical dispensing, however, should not be unconditional. Through a model act,<sup>473</sup> the states

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468. See, e.g., ALA. CODE § 34-21-87 (1975).

469. See, e.g., UNIFORM CONTROLLED SUBSTANCES ACT (1994).

470. Brushwood, *supra* note 268, at 95-96.

471. See, e.g., *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985); *Samuels v. American Cyanamid Co.*, 495 N.Y.S.2d 1006 (Sup. Ct. 1985).

472. See, e.g., *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245 (N.J. 1999).

473. This action was likely guided by the NABP. See, e.g., NAT'L ASS'N OF BDS. OF

must commit themselves to regulating the online pharmacies physically located within their borders.<sup>474</sup> In a 180-degree switch from the current regulatory model, pharmacies with interstate businesses could be required to have an exporting state's certificate requiring, for example, additional reporting and available online post-dispensing advice. The states should establish a clearinghouse for complaints about licensed interstate pharmacies and make those complaints and other quality and performance information publicly available, mimicking the models emerging for informing patients about hospital ratings,<sup>475</sup> nursing home ratings<sup>476</sup> and malpractice/disciplinary proceedings against physicians.<sup>477</sup> Crucially, online prescribers and dispensers should be prohibited from cross-ownership interests or payments, which would be consistent with mainstream health's approach to self-dealing.<sup>478</sup> Online pharmacies should not be permitted to refer to specific online physicians and vice versa.

As for international dispensing, any move to legalize the Canadian connection should be viewed as a red (and white) herring. The fact that pharmaceuticals are less expensive across the northern and southern borders of the United States is not some accident of pharmacy licensing. Congress and the White House, unlike a majority of consumers,<sup>479</sup> do not

PHARMACY, MODEL STATE PHARMACY ACT AND MODEL RULES OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (2003),

<http://www.nabp.net/ftpfiles/NABP01/ModelActJune2003.doc>.

474. See, e.g., N.Y. EDUC. LAW § 6808-b (6) (Consol. 2003). The legislation states:

[T]he department shall not prosecute a complaint or otherwise take formal action against a nonresident establishment based upon delivery of a drug into this state or a violation of law, rule, or regulation of this state if the agency having jurisdiction in the state where the nonresident establishment is based commences action on the violation complained of within one hundred twenty days from the date that the violation was reported.

*Id.*

475. See, e.g., Ceci Connolly, *Pilot Test Will Pay Hospitals for Quality: Government Hopes Care Will Improve*, WASH. POST, July 11, 2003, at A03.

476. See, e.g., Nursing Home Compare, Medicare, at <http://www.medicare.gov/nhcompare/home.asp> (last visited Apr. 17, 2004).

477. See, e.g., *Virginia Board of Medicine's Practitioner Information*, HealthCareProvider, at <http://www.vahealthprovider.com/> (last visited Apr. 17, 2004). See Sandra G. Boodman, *Va. Doc Site Adds Key Info*, WASH. POST, Oct. 16, 2001, at F2.

478. See, e.g., 42 U.S.C. § 1320a-7b(b) (2000) (enacting criminal penalties for Medicare & Medicaid kickbacks); 42 U.S.C. § 1395nn (2000) (creating federal limits on patient referrals).

479. Harris Interactive, *Prescription Drug Prices, Hospital Costs and Doctors' Fees*, HEALTH CARE NEWS, June 13, 2003, at



favor price controls and therefore keep pharmaceutical prices high; it may be bad policy for U.S. consumers to contribute to a disproportionate share of pharmaceutical research and development and profit, but the remedy does not lie in the opening of U.S. borders.<sup>480</sup> Canada may have “become the United States’ favorite drugstore for seniors—and its *de facto* Medicare drug benefit,”<sup>481</sup> but if price controls are to be introduced, they should be implemented directly, not imported. Opening up the heretofore closed U.S. distribution system is not without risk, though the FDA is probably exaggerating it. However, congressional action is merely a political artifice designed to pressure U.S. pharmaceutical interests and the politicians whom they financially support, and it will do nothing to improve the regulatory atmosphere surrounding interstate online prescribing and dispensing. When the dust has cleared, though, the FDA and DEA need to revisit their personal importation safe harbors and strive for greater clarity in, and better synchronization of, their policies.

### *C. Reformulating Self-Regulation*

Self-regulatory or non-governmental systems can fill important needs when applied to novel or emerging business models. Because they are intrinsically more nimble and adaptive than governmental systems and unhampered by regulatory gaps or constitutional concerns, they can inform consumer choice and improve an industry’s quality values prior to the maturation of formal standards. In commodity markets such as

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[http://www.harrisinteractive.com/news/newsletters/healthnews/HI\\_HealthCareNews2003Vol3\\_Iss09.pdf](http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2003Vol3_Iss09.pdf) (noting that fifty-seven percent of those polled think drug prices are unreasonably high and thirty-two percent think that they are somewhat high, while a declining majority of fifty-six percent to thirty-nine percent favors government price controls).

480. This observation may be tempered, if not contradicted, by Frank Lichtenberg’s arguments that sustained high levels of spending on new drugs disproportionately reduces other health costs. See Scott Hensley, *Follow the Money: Money Spent on Latest Drugs Is Worth Cost, Economist Says*, WALL ST. J., Sept. 9, 2003, at D6. A Fraser Institute report predicts that “importing Canadian prices generally into the United States would reduce the profits of research based drug makers to such a degree that they would reduce annual investment in research and development (R&D) by US\$5 billion to US\$15 billion, the latter estimate being almost half of global pharmaceutical R&D for 2002.” John R. Graham, *Prescription Drug Prices in Canada & the US—Part 4, Canadian Prescriptions for American Patients Are Not the Solution*, PUBLIC POLICY SOURCES No. 70 (Sept. 2003), at 3, at <http://www.fraserinstitute.ca/admin/books/files/PrescriptionDrugPricesPart4.pdf>.

481. Gilbert M. Gaul & Mary Pat Flaherty, *Canada Is a Discount Pharmacy for Americans*, WASH. POST, Oct. 23, 2003, at A17.

Internet prescribing that feature near identical consumer interfaces (e-commerce engines) and formularies but have not yet seen the development of trusted brand names, self-regulatory systems can reduce the acute informational asymmetry suffered by consumers.

Measured against these functions and goals, the current crop of self-regulatory systems has failed Internet prescribing and dispensing. The AMA and NABP have done little more than mirror the approach of traditional governmental regulators, adding another layer of entry barriers that deter innovators. Credit should be given to the NABP for its VIPPS system, which translates state licensure into a low-risk, consumer friendly system for distinguishing between general Internet dispensing and lawful e-pharmacies. Its value, however, is overstated; in a world where consumers want information about the relative safety and value of Internet pharmacies, VIPPS merely confirms the existence of a small number of relatively well-known e-pharmacy brand names. URAC also deserves praise; it has pointed to the future of useful content regulation. It leverages a well-known accreditation brand to encourage providers to internalize the costs of content quality assurance, without the cost and complexity of other third-party rating systems.

The logic of the AMA-NABP-URAC approach—approving or accrediting only licensed providers—is unassailable. The question is how those organizations and their policy positions or accrediting systems will react to the liberalization of licensure provisions argued for herein. If the states move to a harmonized online practice certificate model or permit shipments from licensed out-of-state pharmacies, the application of established accreditation systems would drive down consumer information costs and accelerate the market's identification of quality and value in online prescribing and dispensing. Synergies with the proposed regulatory innovations are possible and would be cumulative, for instance, if states made URAC and NABP accreditation a condition of (or substitute for) an exporting license.

#### *D. Opening Lawful Channels and Reimbursement*

The parallel drawn between the “war on drugs” chilling palliative care and the crackdown on Internet medicine is certainly valid,<sup>482</sup> particularly with regard to shared concerns about the supply or diversion of controlled substances. There are even more telling similarities, however, between Internet prescribing and the trading of music files over the Internet using

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482. See Brushwood, *supra* note 268, at 78.

peer-to-peer networks. The lesson learned by the music industry was that a clear legal position,<sup>483</sup> vigorous enforcement in the face of consumer demand,<sup>484</sup> and half-hearted alternatives<sup>485</sup> (e.g., Medem and VIPPS) are insufficient to stop an illegal practice.<sup>486</sup> Government regulation and industry angst and denial have to be supplemented with the development of legal alternatives<sup>487</sup> that approximate the traditional interests of stakeholders<sup>488</sup> by leveraging technology (i.e., embedded but not punitive digital rights management in the case of music, digital certificates and restrictive formularies for online medicine) so that lawful markets can develop, driving down prices and increasing consumer satisfaction within a lawful channel.<sup>489</sup>

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483. See *A&M Records, Inc. v. Napster, Inc.*, 239 F.3d 1004 (9th Cir. 2001) (holding that acts of uploading and downloading files containing copyrighted music violate the copyright holders' distribution and reproduction rights respectively). But see *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 259 F. Supp. 2d 1029 (C.D. Cal. 2003) (finding no contributory or vicarious liability on the part of the distributors of Internet software used by copyright infringers). See generally Kevin Michael Lemley, *Protecting Consumers from Themselves: Alleviating the Market Inequalities Created by Online Copyright Infringement in the Entertainment Industry*, 13 ALB. L.J. SCI. & TECH. 613 (2003) (discussing problems in protecting the record industry from peer-to-peer file sharing and possible ways to overcome such obstacles).

484. Amy Harmon, *Subpoenas Sent to File-Sharers Prompt Anger and Remorse*, N.Y. TIMES, July 28, 2003, at C1.

485. Bob Tedeschi, *Downloading Music over the Internet Without Feeling Like a Criminal*, N.Y. TIMES, June 7, 2003, at A14.

486. See PEW INTERNET PROJECT, PEW INTERNET PROJECT DATA MEMO (2003), [http://www.pewinternet.org/reports/pdfs/PIP\\_Copyright\\_Memo.pdf](http://www.pewinternet.org/reports/pdfs/PIP_Copyright_Memo.pdf) (last visited Apr. 17, 2004) (finding that twenty-six million U.S. adults share and thirty-five million download music files online and that "[t]wo-thirds of those who download music files or share files online say they don't care whether the files are copyrighted or not").

487. E.g., iTunes, at <http://www.apple.com/music/store/> (last visited Apr. 17, 2004); BuyMusic.com, at <http://www.buymusic.com/> (last visited Apr. 17, 2004).

488. "This is a very ugly issue for the pharmaceutical industry," said Humphrey Taylor, chairman of The Harris Poll at Harris Interactive. "As importation of drugs grows—and it looks set to grow a lot more—drug companies run a big risk of making more enemies as they fight to prevent importation. This would fuel the growing backlash against the industry." Harris Interactive, *Drug Companies May Be Headed for a Bruising Battle As Drug Importation Grows*, HEALTH CARE POLL, Oct. 9, 2003, [http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline\\_HI\\_Health-CarePoll2003vol2\\_iss8.pdf](http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline_HI_Health-CarePoll2003vol2_iss8.pdf).

489. See, e.g., Bob Tedeschi, *Services for Downloading Music—Legal and with Making a Profit in Mind—Are Gaining Momentum*, N.Y. TIMES, July 28, 2003, at C5; Sandeep Junnarkar,

As recognized by one state legislature, "The full potential of delivering health care services through telehealth cannot be realized without the assurance of payment for such services and the resolution of existing legal and policy barriers to such payment."<sup>490</sup> For online medicine, the key to developing a robust lawful market, countering technophobia, encouraging physician participation, and eventually, AMA and state board buy-in is *reimbursement*. The current positives are as easy to identify as they are rare. For example, the availability of Medicare payment for teleradiological consults is clearly responsible for the robust state of teleradiology,<sup>491</sup> and in January 2004, the AMA issued a new Current Procedural Terminology (CPT)<sup>492</sup> for billing online care.<sup>493</sup> Overall, development of federal government reimbursement for telehealth has been woefully slow. The Balanced Budget Act of 1997 contained some breakthrough provisions, such as adding codes for reimbursement, but it was too limited because it conditioned reimbursement on certain geographical requirements, shared a single fee between the providers involved, and was not responsive in its listing of eligible presenters to the practicalities of telemedicine. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act 2000<sup>494</sup> increased the number of codes, removed the fee sharing requirement,<sup>495</sup> and increased the population of eligible presenters.<sup>496</sup>

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*Buy.com Founder Launches Music Service*, CNET News.Com, July 22, 2003, at <http://news.com.com/2100-1027-5051609.html?tag=nl> (last visited Apr. 17, 2004); *see also* Amy Harmon, *What Price Music?*, N.Y. TIMES, Oct. 12, 2003, at 2-1; *cf.* Press Release, Jupiter Research, Jupiter Research Cuts Online Music Forecast, but Market Will Still Quadruple to \$3.3 Billion in 2008 (July 28, 2003), <http://www.internet.com/corporate/releases/03.07.28-newjupresearch.html> (last visited Apr. 17, 2004).

490. NEB. REV. STAT. § 71-8502(4) (2003).

491. GUIDE TO ASSESSING TELECOMMUNICATIONS FOR HEALTH CARE, *supra* note 8, at 42.

492. Physicians' Current Procedural Terminology. *See generally* Am. Med. Ass'n, CPT Process – How a Code Becomes a Code, at <http://www.ama-assn.org/ama/pub/category/3882.html> (last updated Nov. 3, 2003).

493. CPT codes were released on January 1, 2004 and will be implemented by July 1, 2004. Am. Med. Ass'n, Category III CPT Codes, at <http://www.ama-assn.org/ama/pub/article/3885-4897.html> (last visited Apr. 17, 2004).

494. 42 U.S.C. § 1395m (2000).

495. *See, e.g.*, 42 U.S.C. § 1395m(A)(B) (2000).

496. The U.S. Code provides that:

Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

*See, e.g.*, 42 U.S.C. § 1395m(C) (2000).

Whether such a funding mandate translates into services depends, however, on the states,<sup>497</sup> and their programs remain quite modest.<sup>498</sup> As a result, telemedicine programs, in particular, tend to be short-lived.<sup>499</sup> Most years, congressional bills seek to nudge the system along,<sup>500</sup> but public sector financing of online care remains modest at best.

Investing public funds in technologically-mediated care is economically and politically difficult. The shift of some services from traditional to more efficient e-health models will not take place overnight, and it will not feature direct or immediate cost substitution.<sup>501</sup> As a result, there are likely to be overlaps and, potentially, increases in costs during the transition, or even long-term as patients respond positively to new services.<sup>502</sup> As with HIPAA's Electronic Data Interchange (EDI) model,<sup>503</sup> we must invest now and look for cost-savings later. And, while the public purse is strained, we need to remove regulatory hurdles that discourage private services from entering the telehealth market.

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497. See Ctrs. for Medicare & Medicaid Svcs., *Medicaid and Telemedicine*, at <http://cms.hhs.gov/states/telemed.asp> (last visited Apr. 17, 2004).

498. See *Legislative, Legal and Policy Issues in Telemedicine & Telehealth*, TIE, at <http://tie.telemed.org/legal/state/#bills> (last visited Apr. 17, 2004); cf. CAL. HEALTH & SAFETY CODE § 1374.13 (West 2003); CAL. WELF. & INST. CODE § 14132.72 (West 2003); CAL. WELF. & INST. CODE § 14132.73 (West 2003); see also COLO. REV. STAT. ANN. § 10-16-123 (West 1999); O.C.G.A. § 50-5-191 to -199 (2002). See generally Ctrs. for Medicare & Medicaid Svcs., *States Where Medicaid Reimbursement of Services Utilizing Telemedicine is Available*, at <http://cms.hhs.gov/states/telelist.asp> (last visited Apr. 17, 2004).

499. Claudio Cipolat & Michael Geiges, *The History of Telemedicine*, in CURRENT PROBLEMS IN DERMATOLOGY 7 (G. Burg Karger ed., 2003).

500. See, e.g., Medicare Telehealth Validation Act of 2003, H.R. 1940, 108th Cong. (2003).

501. See, e.g., P. B. Jacklin et al., *Virtual Outreach: Economic Evaluation of Joint Teleconsultations for Patients Referred by Their General Practitioner for a Specialist Opinion*, 327 BRIT. MED. J. 84 (2003).

502. Alan Greenspan, Chairman of the Federal Reserve, has said:

[W]e know very little about how rapidly medical technology will continue to advance and how those innovations will translate into future spending. To be sure, technological innovations can greatly improve the quality of medical care and can, in theory, reduce the costs of existing treatments. But because medical technology expands the range of treatment options, it also has the potential of adding to overall spending—in some cases, significantly.

*Hearing Before the House Comm. on the Budget*, 108th Cong. 6-7 (2004) (statement of Alan Greenspan, Chairman, Board of Governors of the Federal Reserve System).

503. See *supra* note 387.

## VII. CONCLUSION

The transformation of U.S. healthcare delivery into a more technologically adept model is an immensely complex undertaking. It is also a fragile process. There are powerful stakeholders whose dominance is threatened by disruptive new technologies. These stakeholders' reactions to the cram-down style of regulation used in the HIPAA privacy rules and the way technical compliance rules were substituted for general principles that could have found broader acceptance should suggest to regulators that they may want to adopt alternative approaches in the future.

The introduction of the HIPAA's Electronic Data Interchange, the work of the Institute of Medicine and the Agency for Healthcare Research and Quality, and a growing patient demand for online medical information suggest that e-health has passed its tipping point. Contrary to the fears of many and the exaggerations of some, e-health is not a replacement for traditional healthcare delivery. It will impact primary, secondary, and tertiary care differently, and will be more effective with regard to some types of diagnosis, treatment, and care than with others. Only through controlled experimentation in an innovative environment will the correct mix of traditional and technological services and regulations be discovered.

Much of today's prescribing and dispensing activity on the Internet is not just unlawful, it is bad medicine. Clumsy regulation, however well intended, seriously impedes innovation and experimentation, while the parochial and technophobic attitudes that drive some of the regulatory activity in this area are also unhealthy. As a result, overbroad medical and pharmacy board statutes, regulations, and policies are chilling traditional telemedicine and slowing innovation in safer online models.

Following the dot.com implosion, investments in consumer e-health businesses became relatively dormant. In the interim, consumer expectations and familiarity with the Internet as a source of medical information and services have grown exponentially. When the investments return—and they are expected to return<sup>504</sup>—our regulatory systems will need to embrace this new consumer-generated enthusiasm and improve their tools for distinguishing the online wheat from the chaff.

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504. See Gautum Naik, *England Plans Major Revamp of Health Care*, WALL ST. J., Dec. 3, 2003, at B1 (noting that 2002 U.S. health-care computer spending increased 9.3% to \$23.6 billion); see also Steve Lohr, *Investment in Technology Is Roaring Softly Back*, N.Y. TIMES, Nov. 1, 2003, at C1; Michelle Kessler, *Health Data Mandate Gives Tech a Boost*, USA TODAY, June 8, 2003, at B1.



